SCHOOL OF PUBLIC HEALTH

FACULTY OF HEALTH SCIENCES

UNIVERSITY OF THE WITWATERSRAND

THE PREFERRED ROUTE OF HYSTERECTOMY in women without utero-vaginal prolapse in a poorly resourced setting

A thesis completed by published work, submitted to the School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, in fulfilment of the requirements for the degree

Doctor of Philosophy

by

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DECLARATION

I declare that this thesis is my own work. It is being submitted for the degree of Doctor of Philosophy to the School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa.

This thesis is submitted in the format of published work with a supporting introduction, a literature review, and a discussion.

This work has not been submitted before for any degree or examination at any other university.

Signature:

Andreas Chrysostomou

DEDICATION

This PhD is dedicated to my parents, who under difficult circumstances taught me that perseverance, honesty, and hard work are needed in order to achieve anything in life.

This PhD is also dedicated to the thousands of women who have crossed my path and entrusted me with their lives.

ACKNOWLEDGEMENTS

I offer my sincere gratitude to my co-supervisors, Dr William Edridge and Professor Bruno van Herendael, for all their guidance and time dedicated to making this PhD a reality.

I thank also Professors Franco Guidozzi and Professor Paruk for inspiring me to do this PhD, and walking with me through the early stages of this journey.

My thanks also to Ms Rogene Beukes, for all her support towards completion of this thesis over the years, and assisting with all the publications towards completion of this work

But, above all, I thank my wife and my daughters, for their unwavering support throughout this journey of completing my PhD.

ABSTRACT

Background

Hysterectomy remains one of the most common operative procedures for benign uterine diseases performed in the world. At the Department of Obstetrics and Gynaecology of the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), the rate of vaginal hysterectomy (VH) was 9.8% before the initiation of this study, mainly performed for utero-vaginal prolapse. The main objectives of this investigation was to determine if the use of formal guidelines for selecting the route of hysterectomy, a surgical tree algorithm, and a standardised surgical technique would increase the rate of VH and result in an overall decline in open abdominal hysterectomy (AH). An ancillary to this study would be to define the safety of the VH as compared to laparoscopic assisted vaginal hysterectomy (LAVH), regarding outcome, cost, and complications. Finally, this PhD aims to highlight the favourability and achievability of vaginal hysterectomies, as per international guidelines.

Study Design

This thesis is comprised of seven articles addressing the main objectives of the study. All women admitted to the Department of Obstetrics and Gynaecology at CMJAH between July 2001 and December 2014 for hysterectomy, meeting the guidelines criteria were included. The residents in training, under the supervision of the primary investigator (PI) or specialists with large experience in vaginal surgery performed the VH procedures. The secondary objectives included a retrospective study addressing the outcome and cost difference between VH and LAVH over a period of two years (2015-2016) and a prospective randomised control study from January 2017 to December 2019 comparing VH and LAVH. In addition to the patient characteristics and surgical approach to hysterectomy, length of hospital stay, intra-operative and immediate post-operative complications, and cost were recorded and analysed.

Results

The implementation of the teaching programme has seen an increase in the rate of VH from 9.8% to 19.2% by 2008. By the end of this study, the rate increased to 48.4%. This resulted in an overall decline in open AH from 91.2% to 51.6%. The VH/AH ratio increased from 1/9 at the beginning of the study (July 2001) to 1/1 by its end (December 2014).During the study period, 1143 vaginal procedures (1017 VHs and 126 LAVHs) were performed. The results maintained thereafter with the VH/AH ratio of1/1 (49.7% VH and 50.3%TAH) by the end of

December 2019. Regarding cost analysis, LAVH was found to be more costly mainly due to prolonged operating times and the consumables used. The prospective randomised control study confirmed that both procedures, VH and LAVH, are safe, share the same benefits, and demonstrate no major difference in complication rates and blood loss. In all cases, VH was successfully performed and was less costly. LAVH found to be more expensive mainly to longer operating time and the use of consumables.

Conclusion

The use of institutional guidelines for determining the hysterectomy route, a surgical tree algorithm, and a standardised VH technique resulted in an increased number of VHs performed. This provided an essential opportunity for residents to acquire, improve, and maintain the skills required to perform VH safely. This information has been deliberately disseminated through international guidelines by the author, as the lead author with other collaborators following an exhaustive peer review process.

THESIS OVERVIEW AND STRUCTURE

The thesis was done through the route of thesis via publication, and comprises of two parts: (i) an integrating narrative which provides the background, rationale, methodology, and findings of the research; (ii) the research papers that form part of this PhD. In particular, this research is made up of seven related studies, five of which address two fundamental, interlinked problems facing gynaecology today: how to increase the number of hysterectomies performed vaginally, and how to improve residents' training to achieve proficiency. The integrating narrative is divided into eight chapters:

Chapter one is the background and literature review, and is divided into two sections. The first section is on the evolution of hysterectomy through history which led to the aforementioned problems within gynaecology. We consider that a significant cause of this deficiency in VH proficiency lies in a demonstrable preference amongst practising gynaecologists for abdominal hysterectomy. This is the focus of the second section of the literature review, where we explore the global trends regarding hysterectomy and perform comparisons amongst different routes, emphasising outcomes, complications, blood loss, and cost amongst the different approaches to hysterectomy. Ethical considerations will be also discussed.

Chapter two outlines the rationale for the research, and the overall aims and objectives of this PhD.

Chapter three gives an overview of the methodology used in the seven studies that make up this PhD, with detailed descriptions of the study setting and a summary of the data collection and analysis. Further descriptions of the methodology for each study can be found in the appended Papers 1-7.

Chapter four gives an overview of the results of the thesis

Chapter five provides a synthesis of the key findings from the seven studies and how they address the research objectives.

Chapter six discusses the key cross-cutting themes that emerged from the synthesis of all the data from the seven studies. The discussion section also highlights the contribution of the research on changing the route of hysterectomy towards vaginal hysterectomy nationally and internationally.

Chapter seven: Conclusion and **Chapter eight** : Ethics approval

Synopsis of Research

The literature in Gynaecology for the last 30-40 years highlights the low percentages of hysterectomies performed vaginally, where there are not obvious contraindications. When compared to the other routes of hysterectomy, in terms of performance duration and cost and complication rates, the vaginal route, offers more rapid recovery, return to daily activities, less complications and is more cost effective. The laparoscopic route of hysterectomy appears, recently, to be replacing vaginal hysterectomy as the preferred route, a transformation driven by trade and the ever-expanding fascination with technology. This change in preference has resulted in a generation of surgeons that lack the skill set necessary to perform basic vaginal hysterectomy. These surgeons will therefore refrain from performing a routine vaginal hysterectomy, when it should be the preferred route.

In 2001, the rates of vaginal hysterectomy in our institution were 9, 8%, mainly done in cases of utero-vaginal prolapse. Challenging the existing contraindications to vaginal hysterectomy, introducing a teaching academic program, consisting of clinical guidelines for selecting the patient for vaginal hysterectomy, a surgical tree algorithm in determining the route of hysterectomy and a standardised surgical technique the number of vaginal hysterectomies increased to 48, 4% of all hysterectomies performed in our institution by December 2014.

The newer generation of Gynaecologists appear to ignore existing guidelines and recommendations for VH and prefer to perform LH or TAH in patients with benign uterine pathology who can undergo an uncomplicated VH. A lack of surgical experience and inadequate vaginal hysterectomy training during residency, due in part to lack of standardised surgical technique, are major causes of this low vaginal hysterectomy rate among qualified gynaecologists. The vaginal hysterectomy technique was introduced by the unit at the beginning of the study (2001) and was found to be safe, effective, and easy to teach. It is a standardised technique which will be compared to the main existing techniques used today. In teaching the registrars in training the vaginal hysterectomy technique, we believe that a new generation of vaginal surgeons will emerge, able to perform a vaginal hysterectomy in cases otherwise planned for abdominal or laparoscopic hysterectomy.

This thesis will seek the following:

1. To explore the impact of a 14 years registrar training program in vaginal/laparoscopic hysterectomy on the total number of hysterectomies performed in a tertiary institution in South Africa
2. Additionally, an audit will be conducted on hospital cost as well as on the surgical outcomes of vaginal hysterectomy, in comparison with laparoscopic assisted vaginal hysterectomy. This, as a comparison, will give some indication of the cost of TLH ascompared to VH.
3. Finally, a prospective randomised control trial will be performed, in order to compare the outcome of laparoscopic assisted vaginal hysterectomy to vaginal hysterectomy in the absence of uterine prolapse.
4. Additionally, as complementary part of this thesis a survey about the preferred and actual methods of hysterectomy or current practices among members of the South African Society of Obstetricians and Gynaecologists will be done

RESEARCH OUTPUT AND RECOGNITIONS

A number of articles, presentations, collaborations, and honours are associated with this work. These are summarised in this section.

A. Publications

1. Chrysostomou A. Implications of performing laparoscopic assisted vaginal hysterectomy versus abdominal hysterectomy. S Afr J Obs&Gyn 2008; 13(3):80-86.
2. Chrysostomou A, Djokovic D, Edridge W, van Herendael BJ. Evidence-based guidelines for vaginal hysterectomy of International Society for Gynecologic Endoscopy(ISGE). Eur J Obstet Gynecol. Reprod Biol. 2018; 231:262-267
3. Chrysostomou A, Djokovic D, Edridge W, van Herendael BJ. Evidence-based practical guidelines of International Society for Gynaecologic Endoscopy (ISGE) for vaginal hysterectomy. Eur J Obstet Gynecol. Reprod Biol. 2020; 252:118-126
4. Chrysostomou A, Djokovic D. Preferred and actual methods of hysterectomy: A survey of current practices among members of the South African Society of Obstetricians and Gynaecologists. S Afr J Obs&Gyn 2020;26(1):
5. Chrysostomou A, Maposa I. Cost effectiveness analysis of vaginal hysterectomy as compared to laparoscopic assisted vaginal hysterectomy for non-prolapse uterus in a tertiary institution in South Africa. Submitted for publication in IJROG
6. Chrysostomou A, Djokovic D, Edridge W, Libhaber E, Van Herendael BJ. Formal institutional guidelines to determine the route of hysterectomy in patients with benign disease and non-prolapse uterus promotes vaginal approach. Eur J Obstet Gynecol. Reprod Biol. 2021; 259:133-39.
7. Chrysostomou A, Djokovic D, Edridge W, Libhaber E, Van Herendael BJ. A prospective randomized controlled trial comparing laparoscopic assisted vaginal hysterectomy as opposed to vaginal hysterectomy in the absence of uterine prolapse.EuroJObstetGynecolReprodBiol2021;267:73-78.

B. Presentations

Since data collection began in 2001, a number of talks highlighting the progress of our investigations were presented. Some noteworthy events are included here, listed chronologically with role indicated.

- **2004, September:** Speaker at the 8th regional meeting of the International Society for Gynaecology Endoscopy (ISGE) Cape Town on the "Comparison between LAVH and TAH on suitable patients in a South African hospital setting."
- **2006, March:** Poster presentation at the XV annual congress of the ISGE Buenos Aires Argentina. "Implications of performing LAVH vs TAH on suitable patients in South African hospital setting."
- **2008, October:** Speaker at the SASOG congress Cape Town on the "Implications ofperforming LAVH vs TAH on suitable patients in South African hospital setting."
- **2009,October:**Speaker at the FIGO world Congress, Cape Town, South Africa on the "Implications of performing LAVH vs TAH on suitable patients in South African hospital setting."
- **2012, May:** Speaker at SASOG congress and chaired a meeting: Drakensberg, South Africa. "Implications of performing LAVH on the total number of hysterectomies in atertiary institution in South Africa- 10 years analysis"
- **2012, May:** Actively involved in a 2 days congress "ZileleDobrovic", IASI-Romania: Speaker : "Vaginal and laparoscopic Hysterectomy" and also demonstrated live, LAVH and VH (live surgery)
- **2013, April:** Speaker at the AAGL congress, Cape Town, South Africa "The impact of LAVH on the total number of vaginal hysterectomies in a tertiary institution in South Africa-10 years analysis". Chair a session on Robotic hysterectomy.
- **2014, June:** Speaker at the SASOG congress, Cape Town, South Africa "The impact of LAVH on the total number of Vaginal Hysterectomies in a tertiary institution of South Africa". This was selected as one of the 10 best oral presentations during the congress, as chosen by the editor of SAJOG and publish bythe journal "The impact of LAVH on the total number of vaginal hysterectomies

performed in a tertiary institution in South Africa – 10 years analysis . PDF www.Sasog.co.za. See awards

- **2016, May:** Invited speaker at ISGE-Croatia society of endoscopy and SLS to addressthe topic "The place of vaginal hysterectomy in the era of laparoscopic/robotic hysterectomy". During the congress, PI demonstrated live surgery "vaginal hysterectomy for non-prolapse uterus" This was the only live surgery during the above mentioned congress.
- **2017, November:** Speaker at the Maternal Health Summit on "hysterectomy" Organising Urogynaecology pre-summit workshop where he delivered two lectures: Vaginal hysterectomy for non-prolapse uterus Tips and tricks and Vaginal hysterectomy and native tissue apical repair posterior SSLF
- **2018, April:** ISGE – AFSGE Congress Cameroon – Organise one day workshop on vaginal hysterectomy. During this workshop, PI delivered a lecture "10 steps to perform a safe vaginal hysterectomy for non-prolapse uterus". Live demonstration performing vaginal hysterectomy step-by step. In the same congress PI presented the results of "Survey results on preferences of hysterectomy amongst members of ISGE"
- **2019, August:** Chairperson and organizer of the SAUGA National congress 8-10 August 2019 with International participants. The program included during the first day four workshops. I chaired and presented in one of the workshops" Nearly live management of Pelvic Organ Prolapse" which included " Vaginal hysterectomy for non-prolapse uterus –wits surgical technique"
  -Live surgery the second day
  -and full day lectures on the third day.
- **2020,March:** Actively involved and presented at the recent SASOG congress in Drakensberg. During the congress PI ran a very successful half day workshop on: "Nearly live management of pelvic organ prolapse", which included a lecture on **"**The place of Vaginal hysterectomy in the era of laparoscopic and robotic hysterectomy"-Guidelines for Vaginal hysterectomy and the- results of survey amongst practicing gynaecologist in SA.
- **2020, May**: Croatia- Split: ISGE annual congress "Back to basics in MIGS" Invited key note speaker: "From vaginal hysterectomy to laparoscopic Hysterectomy". Is there a need? Due to Covid-19 postponed for August 2021
- **2020, December:** ISGE webinar: PI Participated with two lectures and Video presentations: - VH for non-prolapse uterus and - VH for POP SSLF

C. Significant awards

- At the SASOG congress in Cape Town 2014 "The impact of LAVH on the total number of Vaginal Hysterectomies in a tertiary institution of South Africa" was presented. It was selected as one of the 10 best oral presentations during the congress, as chosen by the editor of South African Journal of Obstetrics and Gynaecology (SAJOG) and published by the SAJOG journal "The impact of LAVH on the total number of vaginal hysterectomies performed in a tertiary institution in South Africa – 10 years analysis" . PDF www.Sasog.co.za
- Awarded an Honorary member by Romanian society of Obstetricians and Gynaecologists for participation over the years in training minimally invasive gynaecologic surgery and Vaginal hysterectomy
- Received the 2019 Wits Research award(a Witwatersrand University annual award for dedication and achievement in research)

D. Grants and collaborations

Prof A. Chrysostomou as head of urogynaecology and endoscopy unit at CMJAH and University of Witwatersrand collaborated with International Society for Gynecological Endoscopy (ISGE) as a board member 2012-2016 and thereafter 2016-2020 as a head of the" Task Force for vaginal hysterectomy" of the society.
The project of writing the evidence-based guidelines for VH and the practical guidelines (10 steps of safe VH for non-prolapse uterus) was accomplished and adopted by the society.
Both have been published in European Journal of Obstetrics and Gynaecology and Reproductive Biology.

E. Appointments to significant Boards and Societies

Board member ISGE 2012-2016
Ex-co ISGE: Head of " Task Force for VH" 2016-2020

LIST OF ABBREVIATIONS

VH	Vaginal hysterectomy
LAVH	Laparoscopic assisted vaginal hysterectomy
TLH	Total laparoscopic hysterectomy
S-TLH	Sub-total laparoscopic hysterectomy
LH	Laparoscopic hysterectomy
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
MIH	Minimally invasive hysterectomy
TAH	Total abdominal hysterectomy
S-TAH	Sub-total abdominal hysterectomy
AH	Abdominal hysterectomy
MFU	Multifibroid uterus
CPP	Chronic pelvic pain
MEN	Menorrhagia
PMB	Post-menopausal bleeding
HGSIL	High grade squamous epithelial lesions

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: BACKGROUND AND LITERATURE REVIEW

1.1. Hysterectomy: background and literature review

This section will discuss the evolution of hysterectomy through the history, the rate of the different routes of hysterectomy across developed and developing countries. The benefits, operation times, complications, differences in blood loss amongst the different routes of hysterectomy as well as the cost involve.

1.1.1. Hysterectomy throughout history

Hysterectomy dates back to ancient times. Vaginal hysterectomy (VH) was performed by Themison of Athens in 50BC[1]and by Soranus of Ephesus in 120 years AD, by removing an inverted uterus that had become gangrenous[1].This was also mentioned in Alshahavarious' writings of 11th century: "if uterus has prolapsed externally and could not be reinserted, it should be surgically excised"[2]. These hysterectomies were carried out sporadically and only for the reason of uterine prolapse or uterine inversion. However, the bladder and the ureter were often injured and the patient rarely survived.
VH was found in the descriptions of Berengario de Capri of Bologna in the Middle Ages (1470-1550) [3] and the first planned VH was performed by Conrad Langenbeck of Gottingen in 1813. His patient made an uneventful recovery and lived for 26 years after the VH [4]. The first recorded subtotal hysterectomy was performed by Charles Clay in 1843, in Manchester, England [1].

One of the strongest proponents of VH was Noble Sproat Heaney, of Chicago who in 1934 reported a series of 627 VH for benign pelvic disease resulting in death in only three cases [3]. During this period, the first part of the 20th century the VH had fallen out of favour as the general surgeons, not being familiar with the vaginal surgery favoured the abdominal route. The first total abdominal hysterectomy (TAH) was performed by Richardson in 1929 in the United States of America (USA) [1]. Despite Richardson's recommendations, subtotal hysterectomy remained the preferred surgical technique until the late 1940's. Subtotal or supracervical hysterectomies were preferred due to theoretically reduced risk of bladder and ureter injury, as well as avoiding opening the vagina, the risk of contamination with vaginal flora was eliminated. The advent of antibiotics, blood transfusion, modern anaesthesia and the recognition that cancer occasionally developed in the cervical

stump, encouraged the surgeons to carry out TAH. For the next 50 years or so no further conceptual advances in the technique was introduced until the advent of endoscopic surgery. During this period the technique of TAH has improved. The introduction of Pfannenstiel incision with cosmetic results and safety led to the explosive increase of the number of TAH seen today.

The introduction of laparoscopic assisted vaginal hysterectomy (LAVH) in 1984 by Kurt Semm [5,6] and the total laparoscopic hysterectomy (TLH) in 1989 by Reich in 1989[7,8] revolutionised the surgical approach to hysterectomies. Both above authors intention was to decrease the number of hysterectomies performed abdominally and not to replace the VH seen today. We should not forget that these conceptual advancements necessitating new skills and equipment represent a new technique for an old procedure- the VH.

With the introduction of laparoscopic hysterectomy (LH) in the last part of the 20thcentury, the concept of minimally invasive hysterectomy (MIH) emerged. The question is why VH, a long-standing procedure dating back to Themison in 50BC[1], meeting all the parameters of MIH (namely avoidance of large painful abdominal scars, less need for analgesia, rapid recovery and return to daily activities among other benefits) does not hold preferential place amongst surgeons with the TAH/LAVH/TLH routes being the first choice? Another problem that needs to be addressed is why the reimbursement for hysterectomy by medical aids and government budgets is more for TAH/LAVH/TLH and recently robotic hysterectomy (RH), than VH for patients with similar indications and uterine weight?

VH for non-prolapsed uterus is the treatment of choice for many gynaecological patients in whom hysterectomy is indicated. It may be safely executed, and thus, should be offered to a large group of appropriately selected women, who today are operated in the main by the abdominal or laparoscopic approach. All efforts should be directed towards teaching the technique of VH during residency. It is demonstrated in literature that TAH/LAVH/TLH are more costly than VH. [12,13,67,69,80,82,119,120]

1.1.2. Introduction

Hysterectomy remains one of the most common operative procedures for benign uterine diseases performed in the world [9,10]. Yet the route of hysterectomy for benign uterine conditions continues to attract controversy and debate. It can be performed abdominally, vaginally, or laparoscopically, with or without robotic assistance. The

advantages provided by VH, or LH, either TLH or LAVH, over abdominal hysterectomy (AH) include less postoperative pain, less need of analgesia, shorter hospital stay, and more rapid recovery and return to daily activities[11-15]. Additionally, there are fewer intra-operative and postoperative complications reported with vaginal hysterectomy as compared with AH or LH [16-18]. However, AH for benign uterine conditions remains the chosen route world-wide. This preference is largely due to a lack of experience in VH, resulting in surgeons' reluctance to perform VH, especially in patients without uterine prolapse, with uterine fibroids, previous caesarean sections, previous laparotomies, as well as in nulliparous women. Correctly challenging these contraindications may lay the foundation for implementing different approaches towards an increased number of VHs [19-25]. Ethnicity has been suggested to be a contributing factor to consider, when attempting to explain the lower rate of VH in South Africa. In an epidemiological study performed in the USA, the authors found that 75% of the indications for hysterectomy performed among African-Americans were for uterine fibroids, which were not suitable for vaginal hysterectomy [26].

It is estimated that approximately 20% of women living in England and Wales will have undergone a hysterectomy before the age of 55 [25, 26]. Most surgeons perform up to 80% of procedures via the abdominal route [26,27]. The reason for this can partly be explained by personal preference but is often due to a lack of training and experience in vaginal or laparoscopic procedures. This results in surgeons' reluctance to perform VH, particularly in nulliparous women, in the presence of uterine enlargement, and in women with previous pelvic surgery or caesarean section. When compared to other routes of hysterectomy, in terms of operating time, cost and complication rates, the vaginal route offers better results, rapid recovery and return to daily activities. For this reason, the above patient factors should not be considered as contra-indications to performing VH [16-18, 28, 29]. The incidence and prevalence of hysterectomies varies amongst countries. In the USA, almost 600000 hysterectomies are performed yearly for benign disease. In 2007, Wu *et al.* reported on hysterectomy rates in the USA for the year 2003, and found that the abdominal route was the most common (66.1%), followed by vaginal (21.8%) and laparoscopic routes (11.8%)[30].

Hysterectomy remains one of the most frequently performed of all surgical operations, with approximately 100 000 hysterectomies performed per annum in the UK [31],60 000 in France[32], 30 000 in Australia[33], and 5 000 in Denmark[34].

There are, however, marked differences in the prevalence of hysterectomies between countries, from a high of 5.4 per 1000 women in the USA[35], through intermediate levels such as Italy 3.7/1000[36] to a low of 1.8/1000 in Denmark[34,39]. Despite the introduction of alternative therapies such as endometrial ablation procedures and the levonorgestrel intrauterine system (Mirena) for managing menorrhagia, there has been little recent change in these rates in most countries. For example, in the USA, the annual hysterectomy rate remained essentially unchanged at 5.4 per 1000 women between 1990 and 1997[35] to 5.1 per 1000 women in 2004[37, 40]. This contrasts to Denmark where the lifetime prevalence of hysterectomy is very low at 1.8 per 1000 women[34].The advent of endometrial ablation procedures and the introduction of levonorgestrel-containing intrauterine system (Mirena) for managing menorrhagia may explain the low prevalence of hysterectomy in Denmark and in other Scandinavian countries, as well as recently in the UK [38]. When data of hysterectomies performed in the UK were evaluated, the decline in the numbers of hysterectomies performed from 1990 to early 2000 was confirmed, and was regarded as a consequence of the introduction of the alternative methods to hysterectomy mentioned above. However, from 2001 to 2012, the rates of hysterectomy showed a plateau, suggesting that the alternatives to hysterectomy have had their maximal impact on reducing hysterectomy rates [40]. Presumably, there is a point beyond which alternative therapies simply become ineffectual and hysterectomy becomes the only viable option. A decade-long collection of data from the UK demonstrated the same trend of abdominal hysterectomies being five to six times more common than vaginal hysterectomy [41].

However, hysterectomy rates in a poorly resourced setting were found to be lower. An epidemiology study performed by Liu F *etal.* found that the prevalence of hysterectomy in a rural Anyang region in China was 3.31 per 1000 women [42]. The majority of hysterectomies were performed abdominally (84%). However, national data regarding the indication and the surgical approaches for hysterectomy are lacking. An analysis from 4653 cases of hysterectomy performed in the Tongi hospital, China, also revealed that 84% of the hysterectomies were performed abdominally, while 16% were performed vaginally or laparoscopically[43].

Lower rates of hysterectomy have been reported in India, which have been estimated to be between 4 and 6 per 1000 women [44]. The types of hysterectomy reported in a teaching institution in Southern India in 2014 were 75.5% abdominally, followed by 17.8% and 6.6% for the vaginal and laparoscopic routes, respectively [45]. Surprisingly, similar

rates were observed in Canada with 70.2% of hysterectomies performed abdominally, 14% vaginally, and 5.9% laparoscopically) [46].

In Brazil, a retrospective cohort study was carried out from January 2010 to December 2014 analysing all hysterectomies performed, the most commonly used technique was TAH (88%), followed by VH (12%), and LH (0.35%). In this study, the introduction of LH was found to be responsible for the decrease in VH when compared to the previous years, with no effect on the rates of hysterectomies performed abdominally [47].

Variations regarding the type of hysterectomy preferred were found not only between countries, but also between cities, regions, and even hospitals within the same region. As such, difficulty is often experienced when attempting to gauge the preferred route employed by an individual country [48]. To engage with this problem, an audit evaluating the route of hysterectomy chosen to treat women suffering from abnormal uterine bleeding and/or leiomyoma in all Norwegian hospitals was performed. Significant variations in the percentage of abdominal hysterectomies carried out within hospitals were found [49]. Furthermore, a reduction of the overall percentage of abdominal hysterectomies performed was reported, from 75% in 2003 to 62% in 2006 [49].

In general, hospitals with low patient volumes tend to perform more abdominal hysterectomies compared to larger hospitals. In some small hospitals, the percentage of hysterectomies performed via the abdominal route was 100%, whereas in the larger hospitals, this percentage fell to 20%[49].This implies that techniques for minimally invasive hysterectomy (VH and LH) have not yet been adopted by most gynaecologists in smaller departments, in spite of the well-recognised advantages they present.. A comparison of the different types of hysterectomy performed worldwide is shown in Table 1.

Despite the benefits offered by VH, globally70- 80% of hysterectomies have been shown to be carried out via the abdominal approach, according to all large-scale surveys, except when treating utero-vaginal prolapse, for which the vaginal route is generally preferred. This latter indication accounts for about 10% of all hysterectomies conducted worldwide [50]. The rate of LH has been shown to be increasing, without a significant reduction in AHs. This increase in LH has thus been incurred at the expense of VH while, ideally, it is the VH rate that should increase at the expense of both, LH and the AH rate.

Table 1: International comparison of methods of hysterectomy.

Country	**% TAH**	**% VH**	**% LH**
UK	64	30	3
USA	63	29	11
Denmark	80	14	6
Finland	58	18	24
Canada	78	14	5,9
China	84	16	
India	75.5	17.8	6.6
Brazil	88	12	0.35

This decrease in the rate of VH is demonstrated clearly in Australia, where the rates of VH have dropped by 53% between 2001 and 2015 in younger patients and 29% in the older age group [51]. Nigeria demonstrated a further decrease in VH, where the vaginal route was utilised in approximately 12% of hysterectomies performed in a teaching university hospital [52]. In Norway, the preferred route of hysterectomy has changed in favour of LH, where the number of VHs have decreased to below 10%, mainly performed for utero-vaginal prolapse [53]. It is a common perception that the decreasing VH rate, which came about as a consequence of the dependence on LH, may be at least partially attributed to the impact of the industry that manufactures and promotes the laparoscopic equipment. The introduction of robotics has changed the rates in favour of RH, with a further decline not only in VH but also in conventional LH [54].

Most hysterectomies are performed for benign indications such as symptomatic uterine fibroids, abnormal uterine bleeding, endometriosis and uterine prolapse. In the majority of series from around the world, the most common indication for hysterectomy, accounting for about 40% of all hysterectomies, is uterine fibroids [26]. In a study in a tertiary institution in South Africa, uterine fibroids were by far the main indication for hysterectomy [55].

In a study described here we demonstrated that by performing laparoscopies in patients who were considered unsuitable for VH by consultants from other units, meeting the inclusion criteria set by the unit, confidence was gained in pre-operative assessment and more

patients were able to undergo uncomplicated VHs. Adherence to this approach, led to an increase in number of VHs from 9,8% at the beginning of the study(2001) to 19,2% by its end (2003). LAVH can be a vehicle to extend the perspective of the vaginal surgeon, thereby increasing their skill in vaginal surgery and particularly their skill in assessment of vaginal operability. The results of this study have been already published (see article 1).

The newer generation of gynaecologists appear to ignore existing guidelines and recommendations and prefer to perform LH or TAH in patients with benign uterine pathology who can undergo an uncomplicated VH. LH hysterectomy itself is a costly procedure that requires a very skilled surgeon, however LH has three main divisions, depending on the amount of laparoscopic contribution toward VH: LAVH, LH and TLH (see Table2).

Table 2: A brief explanation of the various modes of hysterectomy, LH has three main divisions

1	Laparoscopic assisted vaginal hysterectomy (LAVH), in which a VH is assisted by laparoscopy. The uterus is detached from the adnexae laparoscopically but the procedure does not include uterine artery ligation
2	Laparoscopic Hysterectomy (LH), where the uterine arteries are coagulated and transacted at the mid lower cervical length. For the LAVH and LH the rest of the operation is performed vaginally. After closure of the vaginal vault and peritoneum, laparoscopy is performed to assess and secure haemostasis. It is also crucial to assess for any complications of the procedure and to wash out blood clots and debris
3.	Total Laparoscopic Hysterectomy (TLH), where the entire procedure is performed laparoscopically without any vaginal component. The vault is mandatory to be closed laparoscopically

In South Africa, there is a lack of nationwide statistics. At the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), before the initiation of a laparoscopic training program, VH comprised only 9.8% (July 2001) of all hysterectomies [55]. This was attributed largely to a lack of adequate training. The introduction of an VH/ LAVH teaching program led to an increase in the percentage of VH performed from 9.8% in July 2001 to 19.2% by December 2003 [55]. The introduction of evidence based guidelines in choosing the route of

hysterectomy, a hysterectomy algorithm tree and a standardized VH technique lead to an increase in the rate of VH performed in our institution to 48,4% by the end of December 2014 (see article 6).

The introduction of LH by Harry Reich in 1989 revolutionized the surgical approach to hysterectomies [7]. The main purpose was to allow more hysterectomies planned for abdominal route to be performed vaginally or to make a difficult VH easier. The role of LH however, was not to substitute VH. In the USA, before the introduction of LH, the rates of VH were 22% and rose to 33%, after the introduction of LH. Thus, the rates of LH are reported to be at 11% [35].With the introduction of robotics there has been a further decline not only in the number of VH but also in conventional LH[54]. RH is extremely expensive and is not affordable in most health care systems [54].

LAVH is an important technique to master during residency because it may allow more hysterectomies, otherwise booked for abdominal hysterectomy, to undergo a VH with a minimal laparoscopic component. LAVH has a place where there is uncertainty of a successful VH. LAVH is also necessary in order to carry out adhesiolysis, to treat endometriosis and restore pelvic anatomy. It is also useful when prophylactic oophorectomy is required and the ovaries are not accessible via VH. Kovac SR *et al.* demonstrated that by performing laparoscopies on patients who were considered unsuitable for VH on clinical examination, 93% were rendered eligible for VH on laparoscopic inspection and minimal assistance [56]. In a study by Chrysostomou [55], it was demonstrated that by performing laparoscopies in patients who were considered unsuitable for VH (by specialists from other units in the same hospital), all the subjects were then afforded an uncomplicated VH, though with the assistance of laparoscopy (LAVH).

Adherence to this approach led to an increase in the number of VH from 9.8% in July 2001 to 19.2% in December 2003 at CMJAH. Both the above studies [55,56] reached the same conclusion: the laparoscopic approach should be converted to a vaginal procedure as soon as possible (e.g. after adhesiolysis, treatment of endometriosis, adnexectomy, or location of the fibroids, and any other impediment to VH). Nothing is gained by continuing dissection, since this not only considerably and unnecessary prolongs the surgery but also increases the risk of visceral damage.

1.1.3. Comparison of the different types of hysterectomy

Hysterectomy remains one of the most frequently performed gynaecological procedures in the world. Hysterectomy for benign gynaecological procedures continues to attract controversy and debate. Hysterectomy can be performed abdominally, vaginally, laparoscopically with or without robotic assistance. Fortunately, there is now considerable and rapidly increasing literature based on randomized trials and large prospective studies on which to base opinions. This comparison of the different types of hysterectomy will be based on the existing literature. As compared to AH, VH and LH should be the preferred route of hysterectomy, as they offer the same benefits and avoid large, painful abdominal incisions that are needed for AH, while also avoiding longer hospital stay and a delay in returning to daily activities [11-15] . In a Cochrane review [11], Nieboer*et.al.* found the following found that VH, as compared to AH, is associated with a shorter hospital stay, the ability of the patient to resume normal daily activities more quickly, and less infections and episodes of raised temperature after surgery. LH, as compared to AH, has the same advantages as VH. There was less blood loss and fewer wound infections in LH, as compared to AH. LH took longer and was associated with a greater risk of damaging the ureter or the bladder [11].

No differences were found between LH and VH with regards to their benefits. However, when compared with VH, LH takes 39.3 minutes longer than VH, on average and is associated with a higher rate of complications [11]. Fewer complications have been associated with VH, when comparing this method of hysterectomy to all other routes. In 2015, a further Cochrane review by Aarts *etal* confirmed the findings of Nieboer *et al.* regarding the advantages of VH over the other routes of hysterectomy, including RH. He found that RH presented no difference in outcomes when compared to conventional LH, beneficial or otherwise. Thus, both Cochrane reviews concluded that VH should be considered the first choice for hysterectomy in the treatment of benign conditions [11,15]

It is evident from the literature that there are fewer complications associated with VH, when comparing this method of hysterectomy with the other routes. As compare to AH, VH and LH should be the preferred route of hysterectomy as they offer the same benefits [57,58]and avoid large painful abdominal incisions that are needed for AH, while also avoiding longer hospital stay and delay in returning to daily activities [11,12,59,60]. To evaluate the choice of surgical routes and the associated complications of hysterectomies for benign disorders, David-Montefiore *et al.* [61], reviewed 634 women in a prospective study, evaluating surgical routes and complications of hysterectomy and concluded that intra-and

post-operative complications were significantly more frequent in abdominal and laparoscopic hysterectomies in comparison with vaginal hysterectomies. Therefore, they recommended the use of VH for benign disorders of the uterus.

McPherson *et al* reported on the severe complications related to hysterectomy and concluded that LH was associated with the greatest risk of severe complications, both intra- and post- operatively as compared to AH and VH [62]. Morelli *eta*. conducted a prospective randomized-control trial comparing TLH and VH.TLH was associated with 7% haemorrhages, 2.5% ureteric injuries and 86 minutes operating time compared with VH, which was associated with 2.5% haemorrhage, no ureteric injuries, and an operating time of 46 minutes [63].

In the VALUE national hysterectomy study comparing the three routes of hysterectomy (TAH, VH, and LH), Maresh *etal* found that LH was associated with more visceral complications, major haemorrhage, and return to theatre as compared to VH and TAH [31] Although the laparoscopic complications were not according to the stage of LH performed, the study showed the superiority and safety of VH. The VALUE findings were confirmed two years later by Garry *et al.* in the eVALuate study [12], where two parallel randomized trials were conducted: one comparing LH with AH, and another comparing LH with VH. In the abdominal arm, in which AH was compared with LH, the complication rates for laparoscopic hysterectomy were as high as 11.1%. In the vaginal arm, in which VH was compared with LH, no difference was found in major complications between LH and VH. However, this trial was reported as underpowered and thus inconclusive [12]

The Finnish national register of laparoscopic hysterectomies review and complications of 1165 operations, documented a 3.8% blood transfusion rate with 1.2% vascular complications [64].In the FINHYST study, a prospective study of 5279 hysterectomies performed for benign conditions, Brummer *et al.* found major complications in 11.7% of VH cases as opposed to 15.4% for LH and 19.2% for AH, respectively. The study investigated the rate of urinary tract injuries in detail, and determined that bladder injury occurred in 0.6% of VH cases, and 0.9% and 1% for AH and LH cases, respectively; the rate of ureter injury was 0.04% for VH and 0.3% for both AH and LH. Bowel injury was also less common in VH, with a rate of 0.1%, while AH and LH had injury rates of 0.2% and 0.4%, respectively.

Finally, VH was found to be associated with less intra-operative haemorrhaging: 1.6% of VH cases involved haemorrhage exceeding 1000 ml during surgery, while AH and LH were found haemorrhaging >1000 ml in 5.7% and 3.0% of cases, respectively [65]. These

studies confirm that VH is associated with fewer complications and conversions to open abdominal hysterectomy as compared to LH and is thus recommended for benign disorders of the uterus [61-64]. It was emphasized that complications such as haemorrhage and blood transfusion rates were higher during the learning curve between 2000 and 2005, but decreased thereafter. Similar observations such as a decrease in urological and bowel injuries were found as the skills improved [65-67].

Richardson *et al.* in 1995 evaluated the effect of LH on total operating time and hysterectomy time as opposed to VH. The study found that TLH could take as much as three times longer compared to VH without laparoscopic assistance. They suggested that if LH is done, it should be converted to vaginal procedure as early as possible to reduce the overall operating time. They concluded that LH does seem to be a waste of time for most patients [68]. Ten years later, Johnson *et al* evaluating 27 randomised control trials that included 3643 participants – found that VH was 41,5 minutes faster than LH and that the patients' return to daily activities when VH was performed was similar LH , irrespective of stage [15] It is evident from the literature that VH should be the ideal surgical approach of choice when hysterectomy must be performed for benign uterine disease, wherever possible.

Unfortunately, due to the fact that existing guidelines of selecting patients for VH are not followed and due to the lack of training during residency, many specialists perform the procedure abdominally or utilize laparoscopic hysterectomy to remove uteri that are otherwise feasible to be removed vaginally. Regrettably, the industry has propagated LH at the expense of VH. The rationale for LAVH is to convert an abdominal hysterectomy into a laparoscopic/vaginal procedure or a difficult VH into an easier one and not to replace VH. It is essential to revive the use of VH as it is safer, more economical, has rapid recovery, and less complications among all the routes of hysterectomy.

The guidelines of the American College of Obstetrics and Gynaecology (ACOG) on choosing the route of hysterectomy for benign disease state that, when feasible, VH is the safest and most cost-effective route by which to remove the uterus. LH is an alternative to AH for those women in whom a VH is not indicated or feasible [69]. The AAGL adopted the statement advising that surgeons without requisite training and skills required for the safe performance of vaginal or laparoscopic hysterectomy should enlist the aid of colleagues who do, or should refer patients requiring hysterectomy to such individuals for their surgical care [70].

1.1.4. Comparison amongst hysterectomies route regarding blood loss

The amount of blood loss, as mentioned in subsection 1.1.3, depended on the type of hysterectomy performed. Traditionally, the estimation of blood loss during hysterectomy is done by visual approximation by the anaesthetist by checking the absorbed blood in the swabs and the blood suctioned intra-operatively. Visual estimation of blood loss found to be inaccurate and its continuation in practice is questionable [71]. Another problem which can lead to underestimation of the blood loss is the Trendelenburg position during LH where an amount of blood may rest in the abdominal cavity and is not suctioned [72]. Considering these factors in this study, we decided to assess blood loss between VH and LAVH by determining the Hb concentration the day before and the day after the vaginal or laparoscopic assisted vaginal hysterectomy.

Our results are not in agreement with some studies, which showed that a significant higher blood loss was observed during VH as compared to LAVH [71-73]. A smaller drop in Hb levels of VH, as compared to LAVH and TLH were found by other studies [74, 75]. The problem with these studies [71-75] is that they used a small number of subjects. Ribeiro *et al.* in prospective randomized control study, used 60 patients 20 in each group: AH, LH,VH and found that VH is associated with higher reduction in postoperative erythrocytes and Hb levels[73].McGracken *et al.* found that VH underwent more blood transfusion due to the bleeding as compared to TAH and LH. Also he evaluated small number of subjects, 47 LAVH, 45 TAH and 43 VH [75]. Aniuliene *et al.* analysed if the type of hysterectomy influences complications and found that significant higher blood loss was observed during VH as compared to LH. The blood loss was assessed by visual best estimation by the anaesthetist (195mlVH, 123mlLH [74].

The results of this study confirmed the findings of two recent systematic review and meta-analysis studies that there are no significant differences in blood loss between VH and LH, either TLH or LAVH [76,77]. In order to assess blood loss, these two studies used HB concentration the day before and after surgery. Similarly, the same approach were used in order to assess blood loss in this study. These studies definitely used larger numbers of subjects allowing more accurate estimation of the blood loss amongst vaginal and LAVH. In our prospective study similar we analysed 227 subjects (151 in VH arm and 76 in LAVH arm) and we found no significant differences in blood loss amongst the two procedures (see article 7).

1.1.5. Cost analysis of the different types of hysterectomy

The literature review emphasises that when a hysterectomy is indicated for a patient, the vaginal route should ideally be the route of choice [78, 79]. An analysis on cost effectiveness was undertaken with the eVALuate study, and it revealed that the vaginal approach was more cost-effective when compared to the laparoscopic route, primarily due to the use of disposable instruments in laparoscopy and the longer operating time needed to perform LH as opposed to VH [12]. Sculpher *et al.* found that LH cost an average 780 USD (£599.91) per patient more than VH [80]. With more than 500 000 hysterectomies performed annually in the United States, and more than 100 000 in the United Kingdom, the vaginal approach is more relevant at this time of economic difficulties. In 1998, the Royal College of Obstetricians and Gynaecologists recognised that the route of hysterectomy should be audited to determine the optimal rate of VH [81]. The audit should include surgeon preference, degree of descent of the uterus, and need and opportunity for more training in vaginal surgery [81]. Since then, little has changed in favour of VH. The personal preference of the surgeon should not mask the lack of skills. If the senior specialists in teaching institutions are not comfortable with this procedure, it will result in the registrars/interns in training qualifying as gynaecologists without the appropriate skills. The lack of skills to perform VH during training is considered as the main reason for being inclined to perform hysterectomy by the abdominal route, when it could safely be performed vaginally.

When formal guidelines are used to determine the route of hysterectomy, VH was performed in 90% of the patient treated and in 100% of the patients in whom the pathology was confined to the uterus [67]. In comparison, when formal guidelines were not incorporated in the decision making process, VH was reported in 42% of the patient treated and in 64% of the patients in whom the pathology was confined to the uterus [82]. When guidelines are used to assist clinical decision making, this would have resulted not only in a potential savings of US $1.2 million for every 1000 hysterectomies performed vaginally but also a reduction of 20% in complications associated with the procedure [82]. In a study performed at our institution, it was found that by incorporating guidelines in selecting women for VH, and by following surgical tree algorithm all women schedule for VH, underwent uncomplicated VH. We found that potential savings of 18.4 million ZAR or 1.45 million USD for every 1000 hysterectomies performed vaginally could be made (see article 5).

In conclusion, VH proficiency should not be sacrificed at the expense of LH. Academic institutions worldwide need to review a strategy to retain the skill of VH via

appropriate training programs. The implementation of formal guidelines, surgical tree algorithm and a standardized surgical technique, as those proposed in this manuscript, can lead to a decrease of hysterectomies performed abdominally and a significant increase in hysterectomies performed vaginally without an inappropriate increase in laparoscopic hysterectomy.

1.2. Factors influencing the route of hysterectomy

The second part of Chapter 1 outlines the factors which may influence the decision of choosing the appropriate route of hysterectomy and explained the reason why very few VH are performed today. Additionally it will explain the rationale overall aim and objectives of my PhD. The ethical considerations of choosing the route of hysterectomy will also be addressed in depth.

1.2.2. Factors influencing the route of hysterectomy

Factors that are considered prerequisites for a successful VH are the vaginal accessibility, together with the size and shape of the uterus. The confirmation of pathology confined or not to the uterus, as well as surgeon experience may also influence the route of hysterectomy. Surgeon training and experience have often been deemed a particularly influential leading factor for the selection of the most appropriate approach to hysterectomy. The lack of training in VH has been raised by several authors as being an important factor, with lack of experience in vaginal surgery leading to gynaecologists having a dependence on the abdominal and/or laparoscopic routes when contemplating hysterectomy [83-85].

Training in vaginal surgery during residency is important in order to challenge supposed contraindications to VH. It has been shown that VH can be safely performed in women without uterine prolapse, in those with an enlarged fibroid uterus up to 12 weeks' gestation, in patients with a history of one or more previous caesarean sections, previous laparotomies, premalignant cervical or endometrial pathology, as well as in nulliparous women. Correctly challenging these contraindications may lead to an increased number of VHs [19-25]. The absence of clear guidelines for selecting appropriate candidates for VH, lack of patient knowledge about surgical options for hysterectomy or not informed by the attending physician about the vaginal route of removing the uterus play a role in low numbers of VH

seen today. Gynaecologic surgeons can no longer continue to select the route of hysterectomy based on their preference and training experience. It's our believe that the adoption of clinical guidelines in selecting patients for VH, evidence based practical guidelines and adequate surgical education, the proportion of hysterectomies performed vaginally can be increased [67,69, 85-88] and would lower the rates of open AH, the cost and the complication rate [67,80]. The introduction of practical guidelines in our residents training unit , a step by step approach on how to perform VH (article 3) led to an increased number of VH performed at CMJAH from 9,8% at the beginning of the study to 48,4% at the end of the study period (see article 6).

Aside from personal training, factors that are considered prerequisites for a successful VH are vaginal accessibility, together with the size and mobility of the uterus. The confirmation pathology confined or not confined to the uterus also influences the route of hysterectomy selected [67].

Vaginal accessibility: Vaginal accessibility is determined by assessing 3 key components: the angle of the pubic arch, the shape of the vagina, and the uterine descent.

A pubic arch that is wide, or more than 90 degrees, allows for easier access to the uterus and placement of instruments, facilitating the vaginal approach. A pubic arch of less than 90 degrees however, should not be considered as a contraindication to VH, as it can be overcome with a small 1-2cm posterior midline first degree episiotomy. This small incision can increase the width of the introitus and can be repaired easily with a delayed absorbable suture at the end of the procedure [24,69, 86,87].

The shape of the vagina, especially the breadth of the vaginal apex is best assessed during vaginal examination by placing two fingers in the posterior vaginal fornix and opening them laterally. If the apex is greater than 3 cm in width there is generally adequate access for VH. A wider vaginal apex facilitates a vaginal approach because it provides ample space for anterior and posterior entry and improves lateral visualization of the vasculature [24, 89].

Uterine descent is the final component of vaginal accessibility and can be assessed during a vaginal examination, by asking the patient to perform the Valsalva manoeuvre and observing the movement of the uterus. Descent is measured in relation to the Ischial spines. In general, descent to at least 1cm below the level of the ischial spines is adequate. Lack of descent should not be considered as a contraindication if the patient has adequate vaginal access. Once the patient has been placed under anaesthesia, the uterine descent can be reassessed. Further descent may be achieved by "massaging" the utero-sacral and cardinal ligaments

while downward traction is applied to the cervix, or after detaching the utero-sacral and cardinal ligaments complex from their attachment to the uterus.

Size and the shape of the uterus: Important factors considered to be pre-requisites for a successful VH are the size and shape of the uterus. Uterine size ≤14 weeks on bimanual examination (≤14 cm in length and 9cm in width) or ≤280g on transvaginal ultrasound examination, usually allow for a VH. Intraoperative uterine size reduction is feasible by performing transvaginal uterine morcellation. It is a common believe that uteri up to 12 weeks gestation can be delivered vaginally without any additional reduction procedures. Uterine morcellation can only be performed after the uterine vessels are secure and only by an experienced vaginal surgeon. Many morcellation techniques have been described. The most common are the uterine bivalving (uterus is divided in 2 halves) and uterine coring which decompress the uterus, facilitating descent, lateral mobility and eventual access to the uterine cornua. Vaginal myomectomy can also be performed during VH, facilitating descent and lateral access to the uterine pedicles and cornua. It must be noted that, morcellation techniques require advance surgical skills and are not suitable at the residents' level. The ACOG has stated that VH is indicated for patients with a mobile uterus of less than 12 weeks gestation size [69].

Pathology not confined to the uterus. When pathology is not confined to the uterus, such as adnexal pathology, adhesions, endometriosis and previous gynaecological surgery or if the surgeon is uncertain of successful vaginal removal of the uterus then it is advisable to perform laparoscopy to restore anatomy before undertaking VH. The decision to perform elective salpingo-oophorectomy is not dependent on the route of hysterectomy and is not a contraindication to the performance of VH.

Routine removal of the ovaries and fallopian tubes in women who are not at risk for cancer is not recommended during vaginal hysterectomy but if it is requested or when absolute indications exist (women at high risk for cancer), prophylactic oophorectomy is more successful laparoscopically. The peak presentation of ovarian cancer is during the fifth and sixth decade and the risk of ovarian cancer, in general population, is 20 per 100.000 at age of 50 years, rising to 40 per 100 000 at age 70 years [90,91]. In the absence of ovarian disease and a personal or family history of breast/ovarian carcinoma, the ovaries should be preserved. Retaining the ovaries during vaginal hysterectomy, was found to reduce vasomotor symptoms, the risk of CVD, deficits in the memory (visual and verbal). Keeping the ovaries during hysterectomy was also found to reduce osteoporotic fractures, improve cognitive function, libido and wellbeing [92-100].

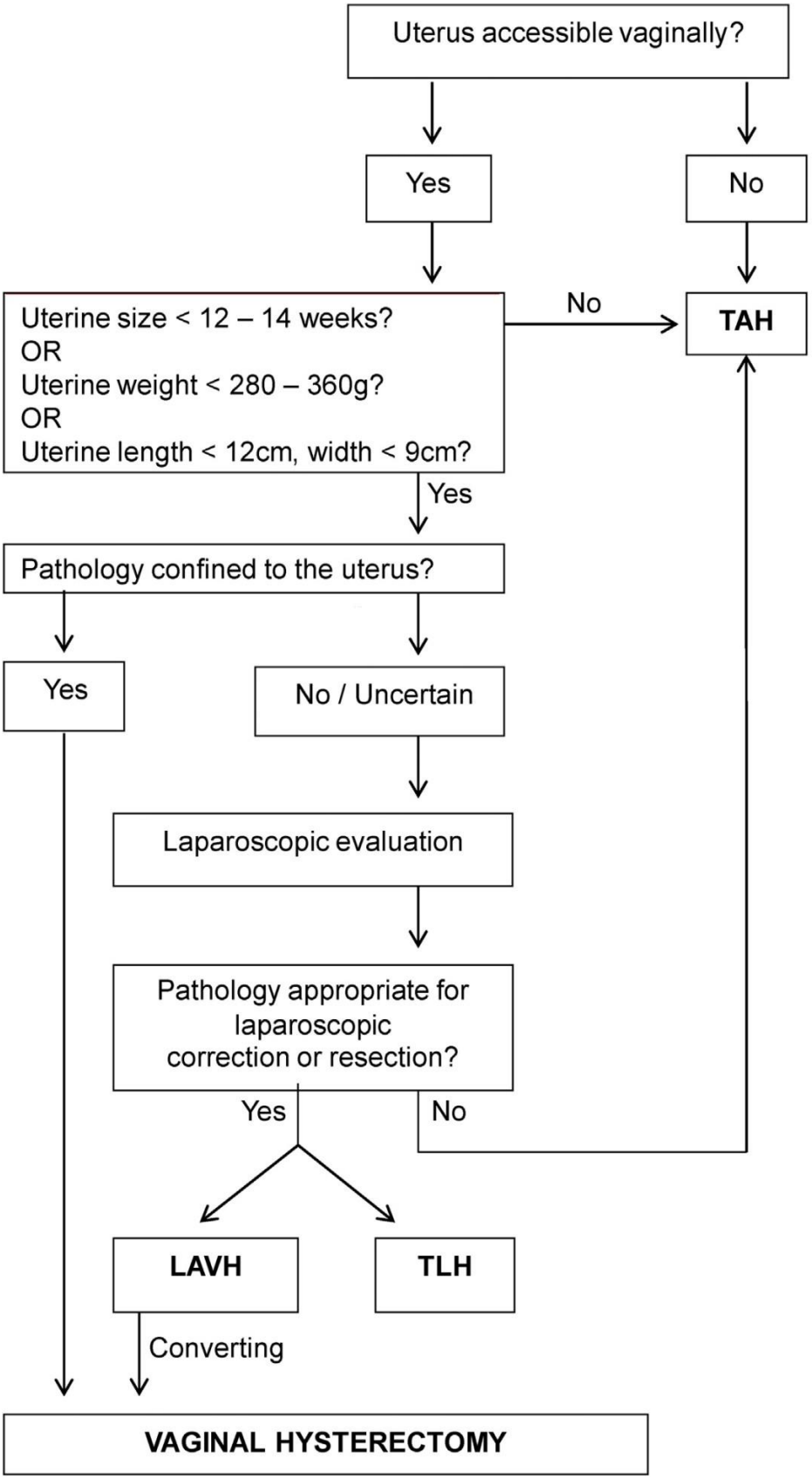
Family history may confer a significant increased risk of epithelial ovarian cancer [97,98].When family history of ovarian and/or breast and bowel cancer suggests a significant risk of carrying a genetic mutation, patients should be referred for genetic counselling [90-92].Removal of the ovaries and Fallopian tubes during VH is recommended in women who are at high risk of developing ovarian cancer. Mandatory salpingectomy is recommended in those who are carriers of the germ line mutation BRCA1 and BRCA2 genes, in which the occurrence of serous tubal intraepithelial carcinoma (STIC) has been established[101]. However, removing the fallopian tubes and ovaries in women with non-proven genetic or familial risk of ovarian cancer cannot be justified in 40-80% of case [101].It is important to consider that prophylactic salpingo-oophorectomy in premenopausal women at low risk for ovarian cancer is associated with a higher risk of developing osteoporosis and cardiovascular disease, and has thus been linked to reduced survival rates [102-107]. Bearing this in mind, in the absence of ovarian disease and personal/family history of breast/ovarian carcinoma, routine removal of the ovaries during VH for benign uterine disease is not recommended, as the risks outweigh the benefits. The performance of prophylactic bilateral salpingectomy with ovarian conservation during vaginal hysterectomy, as suggested by ACOG in 2015 [107], has been found to prevent a diagnosis of ovarian cancer in 1 of every 225 patients undergoing surgery. Furthermore, the implementation of salpingectomy helps prevent death from ovarian cancer in 1 in every 450 women having surgery [101,102].Prophylactic bilateral salpingectomy with ovarian conservation during VH should therefore be undertaken routinely [102].

The success of removing ovaries and Fallopian tubes vaginally varies greatly, and is reported to range between 77% and 91,5% [108-111].Once VH is performed, a moistened pack is gently placed in the pelvis to prevent bowel from obscuring visualization. The transected tube and utero-ovarian ligament are pulled medially into the field until the round ligament is visualised. The round ligament is then clamped, cut and ligated. This allows further descent of the tubo-ovarian pedicle into the field, which can be clamped just above the superior tip of the ovary and then ligated [112]. If there is initial uncertainty surrounding the success in removing the ovaries vaginally, laparoscopic-assisted vaginal hysterectomy (LAVH) should be employed first. Similarly, if a problem arises in removing the ovaries and the tubes during a VH, then laparoscopic assistance should be used to complete the surgery.In certain circumstance, such laparoscopic skills may not be easily obtained.

The surgical tree algorithm for women undergoing hysterectomy for benign indications used in selecting the women for VH or LAVH is shown in Figure 1

The common belief that the ovaries must be removed by the abdominal route or via operative laparoscopy is a myth that can no longer be tolerated if no valid contraindication to transvaginal ovarian removal can be documented.

Figure 1: Guidelines for determining the route of hysterectomy for benign disease (approach based on clinical examination and pelvic ultrasonography).



1.2.3. Background and problem statement

Hysterectomy is one of the most common operative procedures for benign gynaecological diseases. At present, AH constitutes the most common approach However, the advantages of VH are well recognised and include less postoperative pain, reduced need of analgesia, shorter hospital stay, and more rapid recovery and return to daily activities when compared with AH. VH also has fewer intra-operative and post-operative complications reported compared with AH or LH [11-15]. Unfortunately AH for benign uterine conditions remains the preferred route worldwide. It is an interesting observation globally that in most situations the introduction of LH has not shown a significant reduction in AH. The increase in LH has thus been incurred at the expense of a reduction in VH. Ideally the VH rate should increase at the expense of the AH rate. In some instances, the number of VH remained the same, with 20% of operations carried out this way [35,36,39]. It is a common perception that the VH rate has been sacrificed at the expense of LH and it is felt to be attributed to the industry.

A large-scale survey of hysterectomy practice in the USA by Wright *et al* demonstrated a decline in VH between the years 1998 and 2010. The use of VH declined from 24.8% in 1998 to 16.7% in 2010. The use of LH increased to a peak of 15.5% in 2006 and then declined to 8.6%, whereas the use of RH increased from 0.9% in 2008 to 8.2% in 2010 [54]. In large-scale surveys, VH accounts for 10% of all hysterectomies performed numbers of VHs decreased to below 10% mainly performed for utero-vaginal prolapse[53].In a survey performed amongst practicing gynaecologist in South Africa, the reason for the decline in VH given by responders was the lack of training during residency that results in inadequate experience to performed VH once in private practice and the risk of litigation. See Table 3, derived from article published in South Africa Journal of Obstetrics and Gynaecology". The preferred and actual methods of hysterectomy: A survey of current practices among members of the South African Society of Obstetricians and Gynaecologists" S Afr J Obs&Gyn 2020;26(1)[113] (see article 4).

Table 3: In this excerpt from our survey of Ref. [113], practising gynaecologists and obstetricians were asked to rank their reasons for avoiding VH. Here, 1 (5) represents the least (most) significant barrier.

	1	2	3	4	5	Total	Score
Your training registrar time	7.14% 1	28.57% 4	21.43% 3	14.29% 2	28.57% 4	14	2.71
Operating time	25.00% 4	31.25% 5	25.00% 4	18.75% 3	0.00% 0	16	3.63
Your surgical experience	15.00% 3	10.00% 2	10.00% 2	25.00% 5	40.00% 8	20	2.35
Malpractice concerns	23.53% 4	17.65% 3	17.65% 3	41.18% 7	0.00% 0	17	3.24
Other	62.50% 10	6.25% 1	6.25% 1	0.00% 0	25.00% 4	16	3.81

In an article by Antosh *et al.* – a resident's opinions on vaginal hysterectomy training performed in USA in 2011 – only 41.7% of residents reported vaginal hysterectomy as their preferred route of hysterectomy, as compared to 47.1% who preferred Laparoscopic approaches [114]. In an article by Ted L, published in 2013 [115]it was stated that the preference is due to the difficulty in teaching both laparoscopic and vaginal hysterectomy during residency. It was additionally recommended that TLH should be the new gold standard in minimally invasive approaches for hysterectomy. The article concluded that professional societies such as the American College of Obstetrics and Gynaecology (ACOG) and the American Association of Gynaecological Laparoscopy (AAGL) should direct more resources to promote education in and practice of LH if a substantial decrease in AH is truly the primary goal [115]. An improvement of skills in VH was not mentioned. This highlights a fundamental problem currently facing clinical gynaecology: there is a lack of adequate training offered in VH, which will result in a new generation of gynaecologists performing TLH in patients who may have otherwise undergone an uncomplicated VH. The art of performing a VH is dying which is tragic when considering the benefits afforded by this approach.

This data served to provide the impetus for this thesis, which included a study exploring the impact of the introduction of an LAVH teaching program in gynaecology training, which in turn had an impact on clinical skill, and surgical confidence with vaginal surgery. In this way an increase in VH rates and improved patient outcomes were obtained. This study was unique because it was based on extensive and original work in the field of VH

that had not been undertaken before by any institution in South Africa, Africa or internationally. This work was conducted in one centre at CMJAH (urogynaecology and endoscopy unit) over a period of 15 years.

1.2.4. Ethical considerations for this thesis

Hysterectomy is one of the most frequently performed gynaecological procedures in the world. The main indication for hysterectomy, according to studies around the world, remains the fibroid uterus which accounts 40% of all hysterectomies, and excessive menstrual bleeding which accounts for at least one third of the hysterectomies performed today[10]. Open abdominal hysterectomy and vaginal hysterectomy dominated the surgical management of removing the uterus for benign uterine pathology. In spite the fact that VH is associated with better intra- and post-operative outcomes, it remains underutilised and is primarily offered to women with utero-vaginal prolapse. The open AH remains the preferred choice amongst gynaecologist since its introduction. The introduction of LAVH, a new conceptual advancement in hysterectomy, by Kurt Semm in 1984[5,6] and the TLH by Harry Reich in 1989[6,7], shifted the interest towards to minimally invasive hysterectomy (MIH). With the introduction of LH either LAVH or TLH, this new concept of MIH was introduced and strongly marketed by the industry. The benefits of MIH compared to open AH includes avoidance of painful large incisions, less need of analgesia, rapid recovery, faster mobilisation and return to daily activities[11-16]. The ethical dilemma here is why VH, dating back to 50 BC [1,2], which offers the same benefits as LH didn't receive the same enthusiasm received by LH. In this context, it is also important to make note of the fact that VH is associated with less complications as compared to the other routes of hysterectomy, it has less scarring, it is faster, it can be performed with regional anaesthesia (spinal), and is less costly. Additionally, one must recognize that LH is not a new procedure, but rather a new technique for an old procedure- the VH. Another problem that needs to be addressed is why the reimbursement for hysterectomy by medical aids and government budgets is more for AH/LAVH/TLH (and, recently, RH) than for VH for patients with similar indications and uterine weight.

With the rapid growth of new surgical innovations and medical technology, gynaecologists naturally became more invested in furthering their surgical skills. New techniques are taught during short training programs which usually involve substantially high fees, which are not often hands-on, but are frequently virtual stimulators or mannequins.

Ideally, additional hands-on training with approved didactic and realistic courses should be completed, with the actual shadowing and witnessed surgical procedures on real patients by surgeons who are fully accredited and credentialed, with experience in LH.

An unfortunate reality of today is that many gynaecologists have failed to consider the ethical guidelines when recruiting patients for LH as part of their initial training. The learning curve for LH is longer compared to AH or VH and is often associated, at least in the early stages, with very severe complications, which result in prolonged hospital stay and erase the benefits of the procedure[11,27]. The difficulty of teaching the technique during residency in academic institutions is evident in the literature [113,114], therefore once in private practice, the process of learning the new technique must be covered by ethical guidelines and regulations appropriated for the safety of the human subjects of innovative surgery.

Informed consent is one of the most crucial undertakings to take into consideration before deciding to go ahead with any surgical procedure. It is imperative that patients are made fully aware of all potential risks, benefits, alternatives, and costs that are associated with the procedure in question. With regards to associated complications of the various routes of hysterectomies, LH has been associated with the highest rates of complications, most notably visceral, vascular, and urinary tract injuries [16- 18]. On the other end of the spectrum, VH is associated with the least amount of complications. Patients should also be made aware of the possibility of converting the procedure to a laparotomy should complications arise, which would then correlate into increased duration of hospitalisation, and a subsequent increase in financial cost (31,61-65] As has been shown in the literature, VH is less costly whilst still offering the same benefits as LH, and is a comparatively safer procedure. In instances where it would not be feasible to do a VH, LH (either LAVH or TLH) would be preferred to an open AH [69].

One must also consider the ethical conundrum that arises when making a decision between MIHs. A component of this thesis, was the incorporation of a survey which served to evaluate the preferred and actual methods of hysterectomies amongst practicing gynaecologists in South Africa [113]. The survey asked practitioners about their preferred route of hysterectomy (either for themselves or relatives) and found that the majority of participants (86.6%) chose MIH (VH – 46.2%; TLH – 25.4%; LAVH – 15%) with only 8.5% of participants opting for TAH [Fig.1]. Interestingly though, the reality in their practices showed a marked difference in opinion, as TAH was noted to make up the majority of

hysterectomies performed by these practitioners. This staggering difference presents a significant ethical dilemma for practicing gynaecologists, as they are willingly opting not to offer potentially appropriate candidates the hysterectomy that they would choose for themselves or their loved ones. This clearly demonstrated that even though the benefits of MIH (including VH, LAVH, and TLH) are well documented and understood by gynaecologists [Fig.2], the chosen route of procedure remains to be based on surgeon preference as opposed to patient benefit and justice. This was consistent with the ultimate findings of our study, as participants expressed a desire to increase MIH (particularly VH) in their scope of practice[Table5]. Unfortunately, existing guidelines and recommendations of selecting patients for VH have long been ignored.

VH posed a significant problem in the study. The main perceived barrier when it comes to performing VH were a lack of training and experience, with failure to achieve proficiency in VH during residency, followed by concerns of malpractice. In failing to achieve the adequate skills during their residency training, once these doctors are qualified, they will subsequently be unable to teach the future generations of registrars, resulting in poor or lost skills[Table2]. At the same time, once in private practice, these doctors will perform procedures such as TAH or LH, in women who would otherwise have been able to undergo an uncomplicated VH.

This thesis serves to offer a unique opportunity to revive VH by establishing a dedicated vaginal hysterectomy or vaginal surgery unit. Additionally, it has demonstrated that through the introduction of guidelines in selecting appropriate candidates for VH, and by making use of a surgical tree algorithm and standardized surgical techniques, the numbers of VH will increase, thus resulting in a suitable increase in residents achieving the necessary training and proficiency to continue the skill, and improve our future generation of gynaecologists.

Figure 2: Hysterectomy approach preferred for the treatment of hypothetical non-malignant conditions to be applied to respondents or respondents' relatives (S-TAH: subtotal abdominal hysterectomy; S-TLH = subtotal laparoscopic hysterectomy).

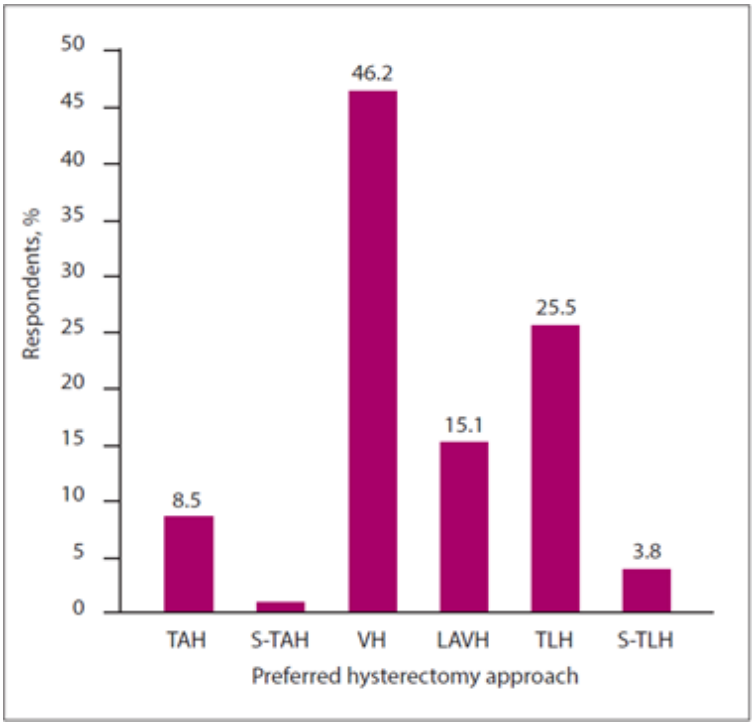


Figure 3: The benefits of vaginal hysterectomy over total abdominal hysterectomy, as perceived by respondents.

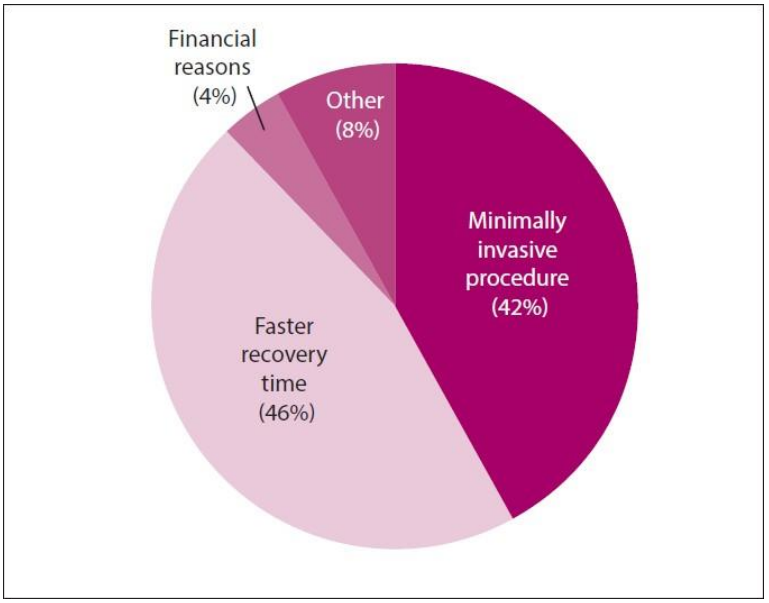


Table 5: Respondents' intended changes regarding the mode of access exploitation when pursuing hysterectomy

Hysterectomy access	Change, *n* (%)			
	To increase	To decrease	To remain unchanged	Total
TAH	5 (4.9)	30 (29.1)	68 (66.0)	103
S-TAB	4 (4.1)	33 (34.4)	59 (61.5)	96
VH	54 (52.4)	3 (2.9)	46 (44.7)	103
LAVH	40 (42.5)	9 (9.6)	45 (47.9)	94
TLH	40 (41.6)	9 (9.4)	47 (49.0)	96
S-TLH	13 (14.0)	22 (23.7)	58 (62.3)	93

TAH = total abdominal hysterectomy; S-TAB = subtotal abdominal hysterectomy; VH =vaginal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; TLH = total laparoscopic hysterectomy; S-TLH = subtotal laparoscopic hysterectomy.

CHAPTER 2: RATIONALE FOR THE RESEARCH AND OVERALL OBJECTIVES

2.1. Research aim

This study aims to eliminate any inconsistencies found in international literature as the majority of these publications are based on multicentre research, involving different surgeons at many different centres which may influence patient outcomes and skew results.

2.2. Hypothesis

The implementation of a dedicated laparoscopic/vaginal hysterectomy teaching program following Urogynaecology and Endoscopy unit formal guidelines, surgical tree algorithm and utilizing a standardized VH technique and (where needed) laparoscopic assistance, will result in an increase in the rate of VH and overall decline in open abdominal hysterectomy. When comparing VH and LAVH the higher cost of laparoscopic equipment together with longer theatre time required for LAVH will highlight the cost effectiveness ofVH (see article 5).

2.3. Study Objectives

The conceptual framework, Figure1, illustrates how the research objectives addressed the increase the number of VH and the overall declined in open AH and LAVH as the experience is gained over a period of 15 years (2001-2014).
This thesis will be divided into three components, in which the following shall be discussed:

Objective 1: To explore the impact of a 14 years registrar training program in vaginal hysterectomy/laparoscopic assisted vaginal hysterectomy on the total number of hysterectomies performed in a tertiary institution in South Africa. To achieve its objectives the unit introduced formal clinical guidelines for vaginal hysterectomy, a clinical decision tree algorithm and a standardized surgical technique. Detail description of the VH technique introduced and followed by the unit in training residents and adopted by ISGE is shown in appendix 1(see article 3).

Objective 2: An audit will be conducted on hospital cost as well as on the surgical outcomes of vaginal hysterectomy, in comparison with laparoscopic assisted vaginal hysterectomy (see article 5).

Objective 3: Finally, a prospective randomised control trial was performed, in order to compare the outcome of laparoscopic assisted vaginal hysterectomy to vaginal hysterectomy in the absence of uterine prolapse. In this prospective randomized control study the differences in blood loss and cost between LAVH and VH were assessed (see article7).

Objective 4: To appeal by the peer review process to an international audience by means of publication and discussion through international fora to support VH as an essential procedure internationally.

CHAPTER 3: METHODS

Chapter3 gives a summary of the methodologies of the three main studies that contributed to this PhD. Details of the methodologies the individual studies are contained in the appended papers 1-7.

There are three main components which contributed to this thesis

Thesis component 1: Retrospective

- To determine the numbers of AH, LAVH and VH per year at CMJAH between July 2001 and December 2014.
- To determine the incidence of complications, including length of hospital stay and short term complications, for VH and LAVH
- To assess whether the use of a laparoscopic/ vaginal hysterectomy training program has had an impact on the incidence of VH performed over the 14-year study period.(see article6)

Thesis component 2: Retrospective

- To determine the differences in hospital costs mainly including equipment used, and the Length of the operation (theatre cost) for patients undergoing VH and LAVH (see article5)

Thesis component 3: Prospective

- To compare operating time and blood loss in patients undergoing VH and LAVH.
- To compare the length of hospital stay and analgesia required postoperatively in patients undergoing VH and LAVH
- To determine the differences in hospital costs and blood loss for patients undergoing VH and LAVH (see article7)

3.1. Study Setting

CMJAH is a tertiary level hospital. The hospital offers Obstetrics and Gynaecological services to the surrounding areas. It is also a referral hospital for the greater Eastern and Western Johannesburg areas. Gynaecological services include an Endoscopy and Pelvic Floor and Endoscopy Unit run by the Principal Investigator.

The Gynaecological service offered is divided into four Units run by qualified gynaecologists. The units are named A, B, C and D. Prior to the study period, units B, C and

D offered general gynaecological services. The majority of patients seen by Unit A are those diagnosed with gynaecological malignancies.
The laparoscopic/vaginal hysterectomy training programme was introduced in 2001 into Unit C, following Guidelines established by the head of the unit and principal investigator (PI) Prof. A Chrysostomou. Units B and D continued to offer general gynaecological hysterectomy for benign uterine conditions.

In order to assess the impact of the laparoscopic/vaginal hysterectomy training programme introduced by unit C; the route of hysterectomy for benign uterine conditions will be assessed against two of the gynaecology units at CMJAH, namely B and D. Due to the nature of the patients and procedures performed, Unit A will be excluded from the comparison.

The numbers of vaginal hysterectomy before the implementation of the training programme introduced by the PI in unit C were compared to the numbers performed over the study period (2001-2014). The numbers of cases of vaginal hysterectomy from unit B and D, will serve as a control to compare to unit C, as Unit B and D did not have the training program implemented.

3.2. Study Design

The study will comprise 2 parts. A retrospective review of patient records was done and data collected for components 1 and 2.This was a descriptive study comparing outcomes of patients undergoing AH, VH or LAVH. Patient records for a 14 year time period (July 2001 to December 2014) were accessed for the first component. For the second component, patient files from Jan 2015 to Dec 2016 were assessed.
A prospective (single-blinded RCT) study was then performed to achieve the objectives for component 3 which started from January 2017 to December 2019.

3.3. Study population/sample size

Component 1 and 2: The study groups included women admitted to Pelvic Floor and Endoscopy Unit for hysterectomy for benign uterine conditions provided they met the following inclusion criteria:

a. Uterine size smaller than or equivalent to a 14-week pregnant uterus on clinical examination.

b. Uterine size less than 14 cm length and 9 cm width on ultrasound examination.

Nulliparous women without uterine descent, women with previous pelvic surgery or caesarean section, women requiring salpingo-oophorectomy and women with cervical dysplasia or pre-malignant conditions will also be included. Women with uterovaginal prolapse who underwent VH were included but analysed separately.
Sample sizes for components 1 and 2 are approximated as 1000 patients and 150 patients, respectively.

Component 3:

The study group includes women admitted for hysterectomy for benign uterine conditions provided that they met the inclusion criteria as above. Exclusion criteria include women with any degree of uterine prolapse (POP-Q $\geq$ Stage II_C).

Women were randomly allocated into two intervention groups: VH and LAVH. The randomization procedure was systematic, and based on a generated list that makes use of serially numbered, opaque envelopes, on a 2:1 basis. Each patient was be allocated a study number and the corresponding envelope was issued to them by a blinded physician. The envelope was opened in the ward, the patient consent and the assigned procedure was undertaken by the surgeon the following day (see article 7). All the VH cases allocated in the study will be performed by the registrar in training. All the LAVH cases allocated in the study were performed by one surgeon (the Principal Investigator). The surgical techniques used for VH and LAVH are discussed separately (Appendix 1 and 2).

Sample size calculation for this component is based on the primary objective: to compare operative time and blood loss for VH and LAVH, based on mean difference of blood loss in VH = 1.4 +/- 1 and mean difference of blood loss in LAVH= 1.8 +/- 1 with an 80% power. Stata 14.1 statistical software was used to determine the minimum sample size required to find significant difference for Satterthwaite's t test assuming unequal variances between the of VH and LAVH, with a ratio of 2/1, knowing that a bigger proportion of hysterectomy cases are done through the vaginal way at the CMJAH.

The sample size required for finding a difference in blood loss between the VH and LAVH, wasat0.05 level of significance, 227 cases in total: 151 VH and 76 LAVH.

3.4. Informed consent

Due to the prospective nature of component 3, informed consent was obtained from each patient for participation in the study. An information sheet was provided and patients were allowed to ask questions pertaining to the Principal Investigator on anything they were unsure of. Any surgical procedure performed requires written consent as per hospital regulations (Appendix 3 and 4)

3.3 Data Collection

Data was collected from patient files with the use of data sheets (Appendices 5, 6, and 7). Specific data sheets was used for each of the three components. However, each data sheet were looked at outcomes including:

- Patient characteristics
- Operative parameters and complications
- Short term clinical outcomes
- Measurement of resources used (Component 2 only)

Data sheet that was used to collect data for all the three components is shown in appendix 5,6 and 7.

The data collected was entered into and analysed with Stata 14.1 software.

3.5. Data analysis

Data was entered into and analysed with Stata 14.1 software. Mean and standard deviation, frequency tables and proportions, and graphs were used to describe the socio-demographic characteristics of the study population. The inferential analysis results were considered to be statistically significant if a p-value <0.05 is obtained (CI 95%).

3.5.1. Component one

Table 5: Objectives of the investigation and the data analysis carried out to meet them for component one.

Objective	Analysis
To determine the numbers of AH, LAVH and VH per year at CMJAH between July 2001 and December 2014	Mean and standard deviations, Frequency tables and proportions were used to describe the demographic and clinical characteristics of the study population. Annual trends of hysterectomies performed were presented using line graphs for AH, VH, and LAVH
To determine the incidence of complications, including length of hospital stay and short term complications, for AH, LAVH, and VH	Frequency tables and proportions were used to describe the distribution of complication outcomes for each hysterectomy route
To assess whether the use of a VH/ LAVH training program has had an impact on the incidence of VH performed over the 14 year time period.	Proportion tests were used to compare the incidence of VH over time

3.5.2. Component two

Tables of frequency and proportions, and graphs (box plots) were used to assess the differences in hospital costs, including equipment used, length of hospital stay, and staff costs for patients who underwent VH and LAVH. The costs were measured in both South African Rand (ZAR) and American dollar (USD) for comparison purposes, and aggregated by the main groups of indication for hysterectomy (Neoplasm, genital cancer, maternal conditions, other, etc.)

3.5.3. Component three

Table 6: Objectives of the investigation and the data analysis carried out to meet them for component three.

Specific Objective	Analysis
To compare operating time and blood loss in patients who underwent VH and LAVH	Two-sample T-test or Mann-Whitney U test were used
To compare the length of hospital stay and analgesia required postoperatively in patients who underwent VH and LAVH	Two-sample T-test or Mann-Whitney U test were used
To determine the differences in hospital costs and blood loss for patients who underwent VHand LAVH	Two-sample T-test or Mann-Whitney U test were used

CHAPTER4: RESULTS

The results highlighted in this chapter reflect the main objectives of this thesis, namely:

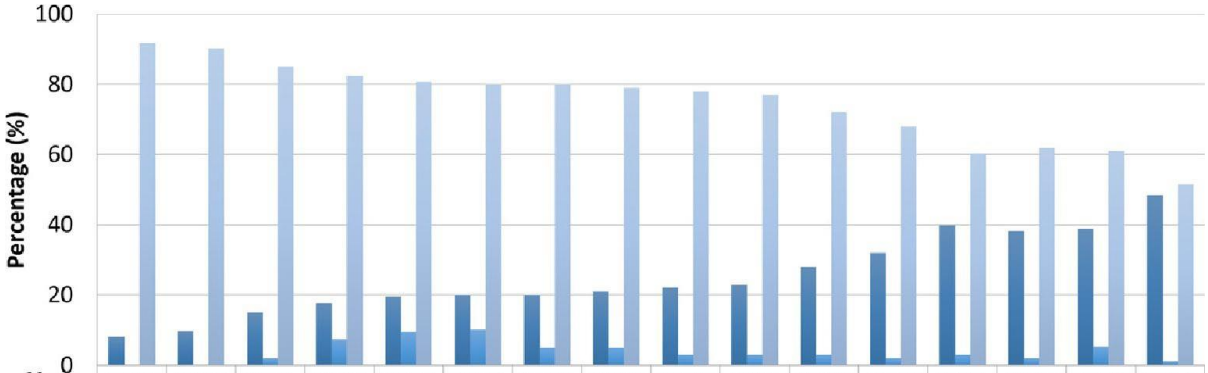
1. The effectiveness of introducing formal guidelines and a standardised VH technique in increasing the number of VHs (and the exposure of registrars to the procedure), and in achieving an overall decline in AH. This covers the 14-year period, and corresponds to component one of this thesis (see article 6).
2. A retrospective cost analysis between LAVH and VH, covering a period of two years. This corresponds to component two of this thesis (see article 5).
3. A prospective randomised control trial comparing LAVH and VH with regards to their outcome, cost, and the blood loss between the procedures. This corresponds to component three (see article 7).

4.1. Component one results

Over the course of the 14-year study period, a total of 3925 women underwent hysterectomy in our department: 2782 (70.8%) had AH, 1017 (26 %)VH, and 126 (3.2%) LAVH. A year before the beginning of the study, the percentage of VH in our Institution was 9.8 % of the total number of hysterectomies performed. The procedure was mainly performed for utero-vaginal prolapse. Introducing formal guidelines, a surgical decision treealgorithm, and a standardised surgical technique (see Panel 1) resulted in an increase in the rate of VH to 48.4 %, and an overall decline in an open AH from 91.2%–51,6% (Fig. 2).

VH to AH ratio increased from 1:9 at the beginning of the study (July 2001) to 1:1 byits end(December 2014). A sharp increase in LAVH was observed from July2001 to December 2004, reaching a maximum of 10.8 %, and dropping to 1,25 % by the end of the period studied (December2014). As experience was gained with VH, the total number of VH increased with a decrease in the need for LAVH (Fig. 2).After following the surgical decision tree algorithm, 1017 VHs and 126 LAVHs were performed in the department during the study period. Thus, 1143 patients submitted to minimally invasive procedures (VH or LAVH) were included in the study. The cases who underwent AH (2782 patients) mainly included women with cervical and endometrial malignancies, and patients with abnormal uterine bleeding not responding to medical treatment and the uterine size exceeding 12 weeksof gestation on clinical examination .

Figure 4:VH, LAVH, and TAH presented as a percentage of all hysterectomies performed at the Department of Obstetrics and Gynaecology of the CMJAH during the period July 1999 - December 2014.



Year	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
VH	8.2	9.8	15	17.6	19.4	20	20	21	22	23	28	32	39.8	38.2	38.9	48.4
LAVH			2	7.2	9.5	10	5	5	3	3	3	2	3	2	5.2	1.2
TAH	91.8	90.2	85	82.4	80.6	80	80	79	78	77	72	68	60.2	61.8	61.1	51.6

Panel 1:VH and LAVH techniques used in the study, where the VH procedure represents the standardised technique introduced by the author and detailed in Appendix 1.

VH:

1. General or regional (spinal) anaesthesia
2. Patient placement in dorsal lithotomy position with her feet in stirrups
3. Exposure of the cervix, circular incision around the cervico-vaginal junction
4. Opening of the anterior and posterior peritoneum, preferentially before the clamping, cutting and ligating of the utero-sacral and cardinal ligaments
5. Clamping, cutting and ligating of the uterine vessel pedicle, containing the uterine artery and vein, and the broad ligament peritoneum anterior and posterior to these vessels, with a 0 or 2.0 delayed absorbable suture
6. Clamping, cutting and ligating of the remaining portion of the broad ligament attached to the uterus (containing the round and ovarian ligaments, the proximal part of the fallopian tube and blood vessels) with 0 or 2.0 delayed absorbable suture
7. Closing the peritoneum and the vaginal
8. Insertion of the urine catheter and vaginal plug

LAVH:

1. Laparoscopic assessment of the pelvic organs, release of adhesions, treatment of endometriosis where necessary, and freeing the adnexa
2. VH as described above, with laparoscope left *in situ* to assess the progress and any complication of the procedure
3. Laparoscopic assessment of haemostasis and removal of the blood clots and debris

The following tables summarise the key characteristics of the patients involved in the study, the relevant indications for hysterectomy, and the outcomes of the procedures. Patients who underwent VH for prolapse, as compared to those who underwent VH for non-prolapse and LAVH, are presented in Table 10.

Table 7: Patient characteristics, where SD refers to standard deviation.

Hysterectomy approach (number of the patients)	**VH (n = 1017)**	**LAVH (n = 126)**
Mean age (SD), years	50.1 (11.9)	43.9 (9.3) *
Parity (SD), number of children	2.7 (1.3)	1,9 (1.0) *
Median uterus weight measured after the surgery (range), g	70.0(20-380)	100.4 *(25-420)

*VH vs LAVH group p-value<0.0001.

Table 8: Indications for hysterectomy

Indication	**VH group, n(%)**	**LAVH group, n(%)**
Cervical dysplasia	541 (53.1)	49 (38.8)
Multifibroid uterus	397 (39.0)	43 (34.1)
Heavy menstrual bleeding	30 (2.9)	16 (12.6)
Post-menopausal bleeding	18 (1.8)	2 (1.5)
Adenomyosis	17 (1,7)	6 (4.8)
Dysfunctional uterine bleeding	9 (0.9)	1 (0.8)
Endometrial polyp, hyperplasia	8 (0.8)	1 (0.8)
Chronic pelvic pain	6 (0.6)	1 (0.8)

Note: patients could have more than one indication each.

Table 9:Comparison of operation time (not including anaesthetic time) and post-operative course between VH for prolapse indications, VH for non-prolapse indications, and LAVH. Here, IQR refers to interquartile range.

Hysterectomy approach	**VH (n = 1017)**	**VH prolapse (n = 123)**	**VH non-prolapse (n= 894)**	**LAVH (n = 126)**
Median operation time Minutes (IQR)	30.1 (20-90)*	30.1 (20-50)*	30.1 (20-45)*	67.2 (50-90)
Median hospital stay Days (IQR)	2.1 (2-4)	2.1 (2-4)	2.1 (2-4)	2.1 (2-4)
Median number of opiate Injections required (IQR)	3.0 (2-4)	3.0 (2-4)	3.0 (2-4)	3.0 (2-4)

* p-value< 0.001 when compared with LAVH group

Table 10: Patient characteristics between VH for prolapse indications, VH for non-prolapse indications, and LAVH groups.

Hysterectomy approach	**VH prolapse (n = 123)**	**VH non-prolapse (n= 894)**	**LAVH (n = 126)**
Mean age (SD), years	63.1 (9.4)	49.2 (11.2)*	43.9 (9.3)*
Median parity (range), number of children	4(1-7)	2(0-5)*	2(0-4)*
Median uterus weight measured after the operation (range), g	42.5 (20-103)	90.4 (20-380)*	100.4 (25-420)*

* p-value< 0.001 when compared with VH prolapse group.

4.2. Component two results

As mentioned previously, this component focused on a comparison specifically between VH and LAVH in the form of a retrospective cost analysis. During the study period, 470 hysterectomies were performed in our department. Out of these, 222 (47.2%) underwent VH. 43 (9.1%) of the VH group have been accomplished with the aid of LAVH. Out of those, 100 patients meeting the inclusion criteria set by the unit and matching in respect to the age, indication, parity, and uterine weight as reported by the department of histopathology were selected and analysed. 60 patients underwent VH and 40 LAVH with a ratio of 1.5:1, knowing that a bigger proportion of hysterectomy cases are done vaginally at the CMJAH. It was imperative that the patients selected possessed sufficiently similar characteristics, in order to allow for sensible and reliable comparisons to be made.

There were no significant differences in age, uterine weight, and parity between VH and LAVH patients. However, the indications were significantly associated with the type of hysterectomy performed (see Table 11). All cases included in the study were successfully performed (no intra- or immediate post-operative complications) and there was no need for conversion to open AH.

The average number of hospital stay days and opiate injections required were both not significantly different between the VH and LAVH groups. However, there was a significant difference between VH and LAVH operation time (measured in minutes) with those who underwent LAVH hysterectomy needing more time 64 min v 31.3 minutes for VH, p-value<0.001 (see Table 12). Consumables used in theatre during LAVH were purchased from three different medical device suppliers (Johnson & Johnson Medical SA, Covidien-Medtronic SA and LigaSure^{TM}). Mover the two years of the study (note that these were not required for VH but only LAVH). There were no significant difference in cost of suture materials used during the two procedures, LAVH and VH (see Table 13).

A summary of the key measures of resources used in the study can be found in Table 13. The mean cost of operation time was equivalent to 193.50 ZAR or 15.3 USD per minute. The LAVH in our study took 32.7 minutes longer than VH; the total cost of extra theatre time needed to perform LAVH as compared to VH was estimated to be 6327.45 ZAR. The mean cost of consumables regularly used by the unit (Trocars, sleeves, Grasper, bipolar tissue sealing, Ligasure™, uterine manipulator) was estimated to be 12 046.09 ZAR. Considering

the extra theatre time and the consumables used during LAVH, an amount of 18 373.54 ZAR or 1458.28 USD more was needed to perform LAVH as opposed to VH for the same indication and uterine weigh. As per the mean exchange rate at January 2015 and December 2016 (1USD= 12,6 ZAR), this is equivalent to 1458.28 USD. As such, VH was much less expensive as compared to LAVH. (Article 5)

Table 11: Patient characteristics, indications for hysterectomy, and the weight of the uteri measured after the operation.

	VH	**LAVH**	**P-value**
N	60	40	
Median age (IQR)	42.5 (37-46.5)	43 (36-46)	0.7480*
Uterus Weight {g}, Median (IQR)	65 (52-74)	57.5 (45.5-70)	0.2067*
Parity {n}, Mean (SD)	2.1 (0.9)	1.9 (1.1)	0.3541#
Indications, n (%)			
Adenomyosis	1 (2.5)	1 (1.7)	
HGSIL	27 (45)	15 (37.5)	
HGSIL/CPP	0 (0)	4 (10)	
HGSIL/MEN	2 (3.3)	0 (0)	
HGSIL/MFU	9 (15)	2 (5)	
HGSIL/MFU/PMB	0 (0)	1 (2.5)	
MEN	1 (1.7)	0 (0)	
MEN/ MFU	3 (5)	7 (17.5)	
MFU	17 (28.3)	10 (25)	0.022+

*Mann-Whitney U Test; #Independent-T Test; +Fishers' Exact Test

Table 12:Comparison of operation time (not including anaesthetic time) between VH and LAVH post -operative course.

	VH	**LAVH**	**P-Value**
N	60	40	
Operation time {min}, Mean (SD)	31.3 (4.6)	64 (10.1)	<0.001
Hospital Stay {days}, Mean (SD)	2.1 (0.32)	2.2 (0.46)	0.2925
Opiate injections required {n}, Mean (Sd)	2.9 (0.28)	3 (0.64)	0.3752

Table 13**:** Estimated variables direct cost per LAVH vs VH.

Resource items	**Estimated cost per procedure (ZAR)**		
	LAVH	**VH**	**Cost difference**
Operating time per minute	12 384.00 ZAR	6 056.55 ZAR	6 327.45 ZAR
Consumables used during procedures	12046.09 ZAR	No consumables	12046.09 ZAR
Sutures used	258.10 ZAR	260.55 ZAR	2.45 ZAR
Pharmaceuticals used during surgery, during post-operative period and discharge *	N/A	N/A	
Ward charges*	N/A	N/A	
Scrap sister and theatre staff +	N/A	N/A	
Specialist Surgeon, assistant Surgeon, anaesthetist time+	N/A	N/A	
Total			**18 373.54 ZAR**

*Disposables used during the procedure are not included in the cost calculation

+.Professional fees were not included in the analysis, as this is a state-run facility with salaried employees.

4.3. Component three results

In this component, a comparison between LAVH and VH was once again performed. Here, however, the study was a prospective randomised control trial comparing the outcome, blood, and cost between the two procedures. 720 women underwent hysterectomy during the three-year study period in our institution: 358 (49.7%) had TAH, 286 (39.7%) VH, and 76 (10.5%) LAVH.A total of227 patients, according to the protocol were included in the study. 151 patients underwent VH and 76 underwent LAVH. The patient characteristics at inclusion, as well as the weights of the uteri among those who underwent VH and LAVH are presented in Table 14.The mean age of the patients who underwent VH and LAVH was 47.1±9.9 and 45.6±8.0, respectively. No statistically significant difference in parity, body mass index (BMI), and uterine weight was observed amongst the two procedures (see Table 14).

The most common indications for VH and LAVH were cervical dysplasia uterine fibroids and menorrhagia, followed by post-menopausal bleeding, adenomyosis, dysfunctional uterine bleeding, endometrial hyperplasia, and chronic pelvic pain (see Table 15). All cases were successfully performed, and there was no need to convert to open AH.

The time required for LAVH was significantly longer as compared to VH, with 62.8± 9.3 minutes needed for LAVH and 29.9±6.6 minutes needed for VH ($p<0.0001$). The average post-operative hospital length of stay and the convalescence time were similar for both procedures. For LAVH, this was 2.2 days (IQR 2-4 days); for VH,2.2 days (IQR 2-4). Post-operative pain and the need of analgesia (Pethidine administration) were similar for both the VH and LAVH groups (see Table 16). As shown in Table 16, there were no statistically significant differences in blood loss between VH and LAVH as determined by a median decrease in serum Hb levels in day one. The pre-operative Hb levels for VH were 13.2gr/dL (12.2-13.6) and the post-operative day one Hb levels were 11,3 (10,6-12,2) gr/dL. For LAVH, the pre-operative Hb was 13,0(11.9-13.9) gr/dL and the post-operative 11,2 (10,0-12,1) gr/dL. The difference of pre-operative and post-operative Hb for VH was1.5 (1-2.2) and for LAVH 1.40 (0.95-2.35), where $p=0.89$ (see Table 16).

Few intra-operative and immediate post-operative complications (three bladder perforations, making up 1.3% of procedures) were observed during the study period, where 2 occurred during VH (1,3% of the 151 cases) and 1 during LAVH (1,3% of the 76 cases). No intra-operative conversion to open AH occurred for either VH or LAVH, and no patient had a relook laparotomy due to bleeding or other reasons in the immediate post-operative period.

The mean cost of consumables is shown in Table 17. The cost of suture materials used during the two procedures, LAVH and VH were similar (see Table 17).A summary of the key resources used in the study and their costs are depicted in Table 17. The mean time of the LAVH in our study took 32.9 minutes longer than VH. The total cost of extra theatre time needed to perform LAVH as compared to VH was estimated to be 6366.15 ZAR. The mean cost of consumables regularly used by the unit as shown in table 4, was estimated to be 9332.05 ZAR. Considering the extra theatre time and the consumables used during LAVH, an amount of 15698.20 ZAR or 1145.85 USD more was needed to perform LAVH as opposed to VH.

Table 14: Patient characteristics.

Hysterectomy approach (number of patients)	VH (n=151)	LAVH (n=76)	p-value
Body mass index(kg/m2) Mean (SD)	29.1 (6.8)	27.4 (6.3)	0.03
Age (years) Mean (SD)	47.1 (9.9)	45.5 (8.0)	0.22
Uterus weight (g) Median (IQR)	71(45-104)	67 (55-114.5)	0.26
Parity Median (IQR)	2 (0-6)	2 (1.5-3)	0.05

Table 15: Indications for hysterectomy, where patients could have more than one indication each.

Indication	**VH group n(%)**	**LAVH group n(%)**	**p-value**
Cervical dysplasia	86(57.3)	46 (61.3)	0.61
Multifibroid uterus	82 (54.6)	42 (56.0)	0.89
Heavy menstrual bleeding	19 (12,6)	16 (21.3)	0.10
Post-menopausal bleeding	4 (2.6)	2(2.7)	1.00
Adenomyosis	9 (6.0)	6 (8.0)	0.77

Table 16: Comparison of operation time (not including anaesthetic time),post-operative course, and differences in blood loss between VH for non-prolapse indications and LAVH.

Hysterectomy approach	**VH (n=151)**	**LAVH (n=76)**	**p- value**
Mean operation time, in minutes (SD)	29.9 (6.6)	62.8 (9.3)	<0.0001+
Hospital stay, median (IQR), days	2 (2-2)	2 (2-3)	0.06 x
Opiate injections required, n (%) 2 3 4	 18 (12) 73 (48) 60 (40)	 0 (0) 39 (51) 37(49)	0.002~
Pre - op Hb, median(IQR) g/dl	13.2 (12.2-13.6)	13.0 (11.9-13.9)	0.42x
Post- op Hb, median (IQR) g/dl	11.3 (10.6-12.2)	11.2 (10.0-12.1)	0.76x
Dif pre-op-post-op Hb, median (IQR) g/dl	1.5 (1-2.2)	1.40 (0.95-2.35)	0.89

+ Student's T-test, ~ Fisher exact test, X Mann White

Table 17:Estimated variables direct cost per LAVH vs VH. Consumables prices in ZAR.

Resource items	**Estimated cost per procedure (ZAR)**		
	LAVH	**VH**	**Cost difference**
Operating time per minute	12151.80 ZAR	5785.65 ZAR	6366.15 ZAR
Consumables used during procedures	9332.50 ZAR	No consumables	9332,50 ZAR
Sutures used	258.10 ZAR	260.55 ZAR	2,45 ZAR
Pharmaceuticals used during surgery, during post-operative period and discharge *	N/A	N/A	
Ward charges*	N/A	N/A	
Scrap sister and theatre staff +	N/A	N/A	
Specialist Surgeon, assistant Surgeon, anaesthetist time+	N/A	N/A	
Total	**21742,40 ZAR**	**6046.20 ZAR**	**15696.20 ZAR**

*Disposables used during the procedure are not included in the cost calculation

+ Professional fees were not included in the analysis, as this is a state-run facility with salaried employees.

CHAPTER 5: SUMMARY AND KEY FINDINGS FROM THE SEVEN STUDIES OF THIS THESIS

This chapter summarises the key findings from the seven studies that contribute to this PhD. Table 18outlines how each of the seven manuscripts addresses the research objectives

The literature in Gynaecology for the last 30-40 years highlights the low percentages of hysterectomies performed vaginally, where there are no obvious contraindications. When compared to the other routes of hysterectomy, in terms of performance duration and cost and complication rates, the vaginal route, offers more rapid recovery, return to daily activities, less complications and is more cost effective. The laparoscopic route of hysterectomy appears, recently, to be replacing vaginal hysterectomy as the preferred route, a transformation driven by trade and the ever-expanding fascination with technology. This change in preference has resulted in a generation of surgeons that lack the skill set necessary to perform basic vaginal hysterectomy. These surgeons will therefore refrain from performing a routine vaginal hysterectomy, when it should be the preferred route.

In 2001, the rates of VH in CMJAH were 9.8%, mainly done in cases of utero-vaginal prolapse. Challenging the existing contraindications to VH, introducing a teaching academic program, consisting of formal clinical guidelines for selecting the patient for VH, a surgical tree algorithm in determining the route of hysterectomy, and a standardised surgical technique, the number of VH increased to 19.8% by December 2004 and 48.4% of all hysterectomies performed at CMJAH by December 2014(see articles 1 and 6).

In the two-year retrospective study (January 2015 to December 2016), VH was found to be less costly as compared to LAVH (see article 5). In the three-year prospective study undertaken by our unit (January 2017 to December 2019), there was no difference observed in the rate of complications and blood loss between VH and LAVH. In this study, VH was also found to be less costly as compared to LAVH. Between 2014 and 2019, the rate of VH has been sustained and remains the same, with the ratio VH/TAH as 1:1(see article 7).

This thesis demonstrates that an improvement in our residents' proficiency with VH can be achieved by addressing the key issues of training and skills maintenance, and by raising awareness of the scientific evidence supporting the use of VH. In particular, we observed an increase in the numbers of hysterectomies performed vaginally after the

introduction of a surgical decision tree algorithm that guides patient selection for VH and the implementation of a standardised vaginal surgical technique. Furthermore, we encountered low complication rates throughout the study period. It is our belief that if other teaching centres follow the strategy we describe here, a substantial shift in the VH:AH ratio can be achieved, in favour of VH.

The newer generation of gynaecologists appear to be unaware of the existing guidelines and recommendations for VH, and seem to prefer to perform LH or TAH in patients with benign uterine pathology who might otherwise undergo an uncomplicated VH. A lack of surgical experience and inadequate VH training during residency, due in part to the absence of a standardised surgical technique, are major causes of this low VH rate among qualified gynaecologists. The standardised technique we developed was compared with the main existing techniques used today. In teaching the registrars-in-training this refined VH technique, we believe that a new generation of vaginal surgeons will emerge, able to perform a VH in cases otherwise planned for AH or LH.

5.1. Overview of the papers contributing to this thesis

Table 18: A list of the thesis manuscripts and the research objectives they address.

Objectives	Manuscripts
Objective1	1. Chrysostomou A. Implications of performing laparoscopic assisted vaginal hysterectomy versus abdominal hysterectomy on suitable patients in South African hospital setting. S Afr J Obs&Gyn 2008; 13(3):80-86.(Cited by 5) 2. Chrysostomou A, Djokovic D, Edridge W, van Herendael BJ. Evidence-based guidelines for vaginal hysterectomy of International Society for GynecologicEndoscopy(ISGE). Eur J Obstet Gynecol. Reprod Biol. 2018; 231:262-267. 3. Chrysostomou A, Djokovic D, Edridge W, van Herendael BJ. Evidence-based practical guidelines of International Society for Gynaecologic Endoscopy(ISGE) for vaginal hysterectomy.Eur J Obstet Gynecol. Reprod Biol. 2020; 252:118-126. 4. Chrysostomou A, Djokovic D. Preferred and actual methods of hysterectomy: A survey of current practices among members of the South African Society of Obstetricians and Gynaecologists. S Afr J Obs&Gyn2020;26(1):29-34. 6. Chrysostomou A, Djokovic D, Edridge W, Libhaber E, Van Herendael BJ. Formal institutional guidelines promotes the vaginal approach to hysterectomy in patients with benign disease and non-prolapsed uterus to determine the route of hysterectomy in patientswith benign disease and non-prolapsed uterus promotes vaginal approach. Eur J Obstet Gynecol. Reprod Biol. 2021; 259:133-139

Objective2	5. Chrysostomou A, Maposa I. Cost analysis of vaginal hysterectomy as compared to laparoscopic assisted vaginal hysterectomy for non-prolapsed uterus in a tertiary institution in South Africa, Sent for Publication IJROG
Objective 3	7. Chrysostomou A, Djokovic D, Edridge W, Libhaber E, Van Herendael BJ. A prospectiverandomized controlled trial comparing laparoscopic assisted vaginal hysterectomy as opposed to vaginal hysterectomy in the absence of uterine prolapse. Eur J Obstet Gynecol. Reprod Biol. 2021; 267:73-78

As explained in section 3, the objectives of these studies were as follows:

1 To determine the numbers of AH, LAVH, and VH per year at CMJAH between July 2001 and December 2014

2 To determine the incidence of complications, including length of hospital stay and short term complications, for AH, LAVH, and VH

3 To assess whether the use of a VH/LAVH training program has had an impact on the incidence of VH performed over the 14 year time period.

Detailed results and findings from each study are presented in the individual papers – see Appendices 1-7.

Paper1

Here, we describe the progress made in the implementation of a teaching programme based on the inclusion criteria and guidelines in patient selection (for women without uterine prolapse) for the route of hysterectomy. The surgical decision tree algorithm and the vaginal surgical technique introduced by our unit were tested. In this study, it was demonstrated that by performing laparoscopies in patients who were considered unsuitable for VH (by specialists from other units in the same hospital), all the subjects were then afforded an uncomplicated vaginal hysterectomy with the assistance of laparoscopy (LAVH). There was shorter hospital stay, less need of analgesia, less intra-operative bleeding and better patient satisfaction with LAVH. Moreover, LAVH decrease the number of hysterectomies done abdominally. This suggests that following guidelines will increase the currently declining rates of VH.

Paper 2

Guidelines were established by the International Society for Gynecologic Endoscopy (ISGE) which detail evidence-based recommendations on the selection of women in whom vaginal hysterectomy for non-prolapse uterus can be safely performed. Six recommendations on patient selection for VH were established. It was determined that VH should be considered as the first choice for benign indications. Conditions commonly cited in the literature as contraindications to VH should not be considered motivations for open AH. Hysterectomy for benign causes is best performed vaginally if the uterus is less than 12 weeks gestation or ≤ 280gr, if accessible vaginally and the pathology is confined to the uterus. The laparoscopic approach should be considered when vaginal hysterectomy is contraindicated or not technically possible.

Paper 3

Guidelines were written for ISGE to provide evidence-based recommendations in the steps that should be taken when performing a vaginal hysterectomy for a non-prolapse uterus. In this study our VH technique was compared with the existing literature. Six recommendations on surgical steps during VH, including two grade IB and four grade IC recommendations, were established.

Paper 4

In this survey performed amongst SASOG members, we found that their preferences for the routes of hysterectomy compared with their actual practice appear inconsistent. The large discrepancy between practice and preference indicates that the route of surgery is more dependent on the clinical preference of the gynaecologist than the medical and clinical condition. The most significant reported barriers to performing VH or LH were a lack of surgical experience due to inadequate training during residency, followed by the risk of complications resulting in malpractice concerns. The responders considered VH, followed by LH, the most ideal mode of access when performing hysterectomy, recognising the benefits of MIH over TAH. The reality, once in private practice the majority of the responders indicated a reluctance to decrease the frequency of TAH. Failure to achieve proficiency during training as a registrar was demonstrated in this survey as a severe obstacle to performing VH.

Paper 5

This study demonstrates that LAVH is unlikely to be considered cost effective when compared to VH for women undergoing hysterectomy for the same indication and uterine weigh. Longer operating time and operating room costs, as well as the expenses of the equipment to perform LAVH, were the main sources of additional cost in LAVH. Longer operating time and operating room costs, as well as the expenses of the equipment required to perform LAVH, were the main sources of additional cost in LAVH.

Paper 6

This study demonstrates that by introducing formal guidelines, a surgical decision tree algorithm, and a standardised vaginal surgical technique -- as well as the incorporation of the guidelines into the resident training programme -- increased the rate of VH and result in an overall decline in open AH.

Paper 7

This was a prospective randomised control trial comparing LAVH as opposed to VH in the absence of uterine prolapse. This study demonstrated that there were no significant differences in blood loss between VH and LAVH. VH was found to be less costly compared to LAVH, primarily due to the difference in operating time and the need for disposable instruments during LAVH. VH for non-prolapse uterus was determined to be safe, offering the same benefits of short hospital stay, rapid recovery and need analgesia as LAVH

The detail on the key findings for each study will reflect in the depth of data collected and analysis done for each study. There were four overarching themes that emerged from these studies, and these will be discussed in depth in the discussion section. The four themes are: the extremely low rate of VH in our institution before the initiation of the study. The lack of training and experience was identified as the main cause of not performing VH in absence of uterine prolapse. The implementation of an academic training program based on introduction of formal guidelines in selecting women for hysterectomy following a surgical tree algorithm developed by the unit. The introduction of a standardized surgical technique which will be compared to the main existing techniques used today for VH. The impact of

such policy on total number of VH performed as opposed to open AH over a period of 14years.Evaluation of such a policy in maintaining the good results five years later, December 2019.

5.2. Key clinical findings

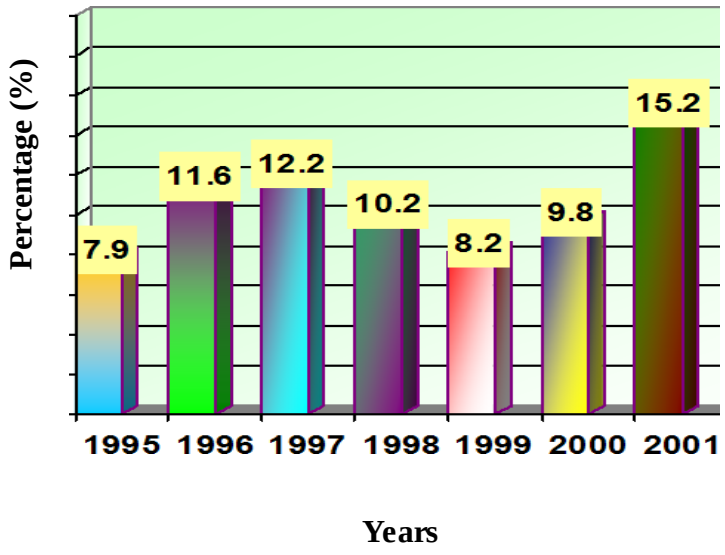
The successful implementation of an academic training program based on the introduction of formal guidelines in selecting women for hysterectomy, following a surgical tree algorithm developed by the unit (Figure 1), and the introduction of a standardized surgical technique lead to an increase on the rate of VH from 9.8% at the beginning of the study in 2001 to 19.8% by December 2014 (Figure 2) and to 48.4% by December 2014 (Figure3). These promising results continue after the completion of the study in December 2014, maintaining the same rate of VH 48.2% as opposed to 51.8% open AH. Thus, the ratio of VH to TAH remains 1:1 through the five year period after completion of the study, in 2019 (Figure 4).

CHAPTER 6: DISCUSSION

This thesis demonstrates that the introduction of formal guidelines, a clinical decision tree algorithm, and a standardised surgical technique into the residents' training programme can increase the rate of VH and result in an overall decline in open AH and LAVH. Though guidelines and recommendations in determining the optimal route of hysterectomy for benign indications can be found within the literature (such as those issued by the ACOG in 2009 [69] and reaffirmed in 2019 [116], these seem to be largely neglected by practising gynaecologists. Global trends have indicated a significant underutilisation of VH, which we believe stems from a lack of training during residency: in not attaining VH proficiency during residency, and subsequent experience in the technique while beginning to practise as a specialist, gynaecologists tend to select a mode of access for hysterectomy based on their preferences rather than standardised selection criteria for the route of hysterectomy.

This is especially problematic due to the variety of contexts in which VH can be applied. Existing guidelines and recommendations promoting VH have been ignored over the years (69,70 , 81) and resulted to elevated numbers of TAH seen today worldwide [119]. This was also observed in our institution before the initiation of this study in July 2001: 9.8% of all hysterectomies performed were vaginal, mainly in cases of utero-vaginal prolapse; the remaining 90.2% of hysterectomies were TAH (i.e. the VH to AH ratio was 1:9), as shown in Figure 6.

Figure 6: Percentage of hysterectomies performed vaginally at CMJAH before the initiation of the study (July 2001).



Teaching institutions, which should be the trend-setters, unfortunately perform most hysterectomies abdominally. Senior gynaecologists inexperienced with the VH who fail to teach residents the VH technique contribute substantially to the vicious cycle seen today, where VH is performed only for a prolapsed uterus. In the absence of prolapse, the majority of the hysterectomies are performed openly or laparoscopically, even if VH is a viable (or even optimal) option [50].

This thesis has shown that successful implementation of an academic training programme in a teaching institution can result in the improvement of VH skills amongst our residents and can thereby improve service delivery in thousands of women undergoing hysterectomy, not only in our setting but also nationally and internationally.

With the commitment of our unit to improving the rates of VH in our institution, the training programme and the implementation of guidelines in selecting the route of hysterectomy, a surgical tree algorithm (see Figure 1) and a standardised surgical technique (see Appendix 1), our study began in July 2001. According to the guidelines set by the unit, any patient (meeting the study's inclusion criteria) admitted for TAH by the consultants of other units in our institution, was first consulted with the aid of the surgical tree algorithm before hysterectomy was undertaken. The inclusion criteria included benign uterine pathology and/or premalignant cervical or endometrial dysplasia. Patients presenting a non-prolapsed uterus, nulliparity, fibroid or enlarge uterus not exceeding 14-week gestation size or 14 cm width/9cm depth on ultrasound examination, and/or previous pelvic surgery were also included. All cases guided to VH by the surgical tree algorithm have been successfully performed. Initially, at the beginning of the study (July 2001 to July 2003), half of the VHs performed were assisted by LAVH. In following this approach, we managed almost to double the number of VHs from 9.8 % in July 2001 to 19.4% by December 2003 (see Figure 7). Therefore, the VH to AH ratio of 1:9 at the beginning of the study (July 2001) reached 1:5 (19.4% VH to 80.6,% TAH) by December 2003 (see article 1).

Figure 1can assist in determining the route of hysterectomy for benign disease based on an approach comprised of clinical examination and pelvic ultrasound. LAVH has its place where there is uncertainty of a successful VH, or in order to perform adhesiolysis, to treat endometriosis, and to restore pelvic anatomy. LAVH is especially needed when prophylactic oophorectomy is required, as it is not always possible for the ovaries to be removed vaginally. Kovac *et al.* demonstrated that of patients considered to be unsuitable for VH on

clinical examination (who were then treated laparoscopically), 98% were rendered eligible for an uncomplicated VH [56]. In a study by Chrysostomou, it was demonstrated that by performing LAVH in patients who were traditionally considered unsuitable for VH, all the subjects were able to proceed to an uncomplicated VH [55]. Both the above authors reached the same conclusion: that the laparoscopic approach should be converted to a vaginal procedure as soon as possible (e.g. after adhesiolysis, treatment of endometriosis, adnexectomy, location of the fibroids) [55, 56]. Nothing is gained by continuing laparoscopic dissection, as this unnecessarily prolongs the surgery and increases the risk of visceral damage. As the surgeon's confidence increases, ultimately more cases can be achieved by VH alone, and the overall operative risks may thus be decreased.

It is our belief − informed by the evidence produced within this thesis − that LAVH is the ideal way to avoid open AH. As mentioned, LAVH was utilised when there was any uncertainty about the success of VH in all cases undertaken by the unit. Based on our experience, and in agreement with other studies, we advise that LAVH or LH should be converted to a vaginal procedure as early as possible to reduce the overall operating time and complication rates [27,55, 56, 68,117]. Longer operating time and the risk of complications were found to be correlated with LH, either LAVH or TLH. Extending the laparoscopic approach does seem to be a waste of time for most patients who could have otherwise undergone uncomplicated VH [68].

Three overarching topics emerged from the seven studies that make up this thesis. Figure 1 illustrates how these contribute to the increase of VH rates and the improvement ofteaching at the registrar level.

These overarching topics are as follows:

1. The establishment of a standardised, algorithmic approach to hysterectomy
    1.1. The introduction of a surgical decision tree algorithm to help guide the surgeon to the appropriate hysterectomy procedure
    1.2. The development of guidelines in selecting women without uterine prolapse who can undergo an uncomplicated VH
    1.3. The design of a safe standardised surgical technique that can be easily taught to residents-in-training
2. A comparison between LAVH and VH
    2.1. A retrospective study on the cost difference between VH and LAVH

2.2. A prospective randomised control trial involving cost analysis and blood loss evaluation between VH and LAVH

3. An audit undertaken by the unit to assess the perceived barriers in performing VH amongst practicing gynaecologists in SA.

In the next sections, we will discuss the problems facing gynaecologists today regarding the low rate of VH, the intervention taken by a dedicated unit in vaginal and minimally invasive hysterectomy, the results of such intervention in increasing the numbers of VH performed relative to open AH and LH, and improving training and proficiency in VH amongst our residents.

6.1. The effect of introducing evidence-based guidelines in choosing the route of hysterectomy for benign disease, a surgical decision tree algorithm and standardized surgical technique

The rate of VHs performed in our institution before the initiation of this study in July 2001 was less than 10%, similar to the rates reported within the international literature, and was reserved only for patients presenting with utero-vaginal prolapse [26,27,30] (see Figure 6**).**

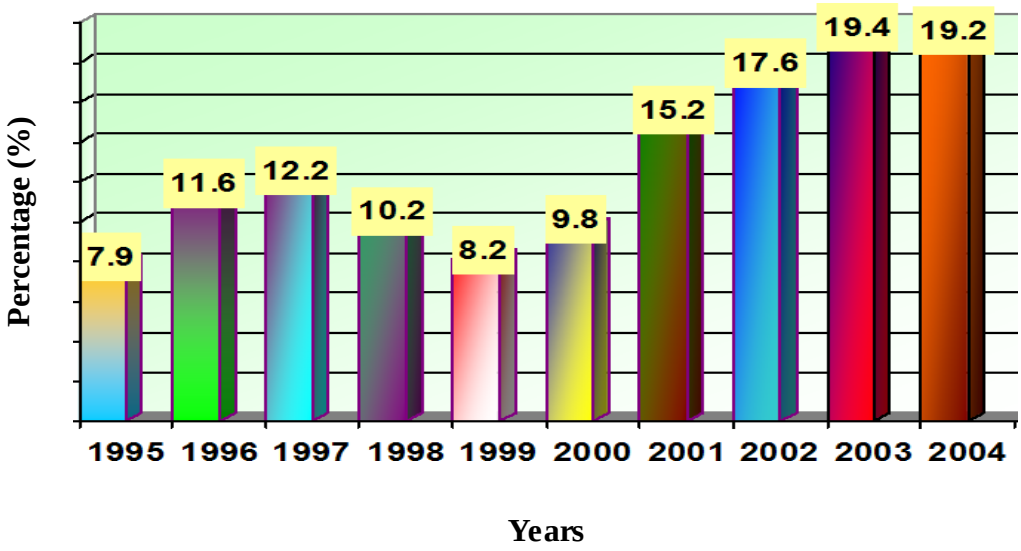
As a result of this policy, all cases of benign uterine disease, or premalignant cervical or endometrial pathology, were operated with open AH (TAH). At that time, it was becoming apparent that such a policy was not justified, as there were already reports that VH was a feasible alternative for a non-prolapsed uterus; VH was also successfully reported in women with an enlarged uterus [19, 20], in women with previous caesarean section(s) [21], in nulliparous women [20,22], and in women with a previous abdominal surgery or who required oophorectomy [24].

The first step taken by the unit was to establish guidelines based on the uterine size, accessibility, and the presence or absence of extra uterine pathology. The second step was to include women necessitating hysterectomy for benign uterine conditions (meeting the inclusion criteria) into the surgical tree algorithm for VH with or without laparoscopic assistance. As shown in Figure 1, any women admitted for hysterectomy for benign uterine conditions was first screened with respect to the specified inclusion criteria set by our unit; if

these were met, the patient was enrolled for VH. Nulliparous women, women without uterine descent, women with previous pelvic surgery or caesarean section, women requiring salpingo-oophorectomy, and women with cervical dysplasia or pre-malignant conditions of the cervix or endometrium, were included in our study. Women with utero-vaginal prolapse who underwent VH were also included but analysed separately (see article 1).

We believe that in order to change the existing mindset regarding the choice of the route of hysterectomy, it was necessary to have a unit dedicated to MIH (VH and LAVH). In the case of our urogynaecology and endoscopy unit, this has been the priority since the unit was first set up by the PI. We consider the results of implementing such a policy in our unit to be very promising, since the rate of VH had increased from 9.8% in July 2001 to 19.2% by December 2003 (see Figure 7).

Figure 7: Percentage of hysterectomies performed vaginally at CMJAH after the initiation of the study (July 2001).

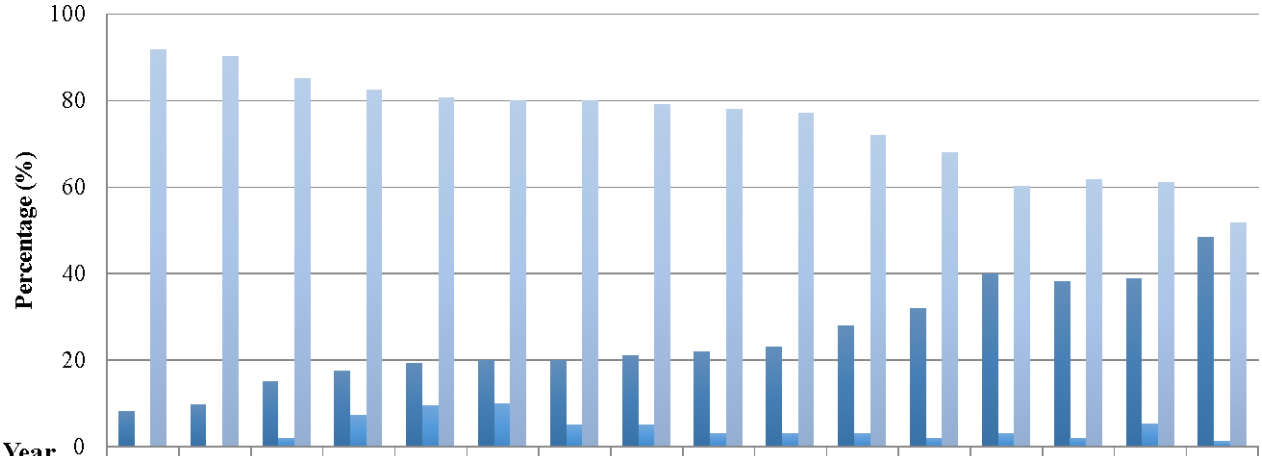


We now consider the overall investigation, spanning from July 2001 to December 2014 (see article 6). This study reinforces the evidence that the use of formal guidelines, a clinical decision tree algorithm, and a standardised surgical technique, as well as the incorporation of these guidelines into the residents training programme, can increase the rate of VH and result in an overall decline in open AH and LAVH. This study is in agreement with other large studies, which indicate that the implementation of a clinical pathway and hysterectomy guidelines can be associated with a decrease in the proportion of hysterectomies performed abdominally [55,67,87]. In our institution, the data from the

beginning of the study in July 2001 its end in December 2014 revealed that the proportion of hysterectomies performed abdominally decreased from91.2% to 51.6% while those performed vaginally increased from 9.8% to48.4% (see Figure 8). The VH to AH ratio therefore increased from 1:9 to 1:1. Based on this, it seems that as much as 40%of feasible vaginal procedures had been performed by more invasive approach like AH before the initiation of the study, in the absence of the surgical decision tree algorithm.

A sharp increase in LAVH was observed from July 2001 to December 2004, reaching a maximum of 10.8%, and dropping to 1.25% by the end of the period studied (December 2014). In Figure 8, we see explicitly that as VH increased, the need of LAVH decreased. This may be explained by a gain in VH experience: as surgeons became more confident in carrying out an uncomplicated VH, they became less reliant on LAVH.

Figure 8: VH, LAVH, and TAH presented as a percentage of all hysterectomies performed at CMJAH during the period July 2001 – December 2014.



Year	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
VH	8,2	9,8	15	17,6	19,4	20	20	21	22	23	28	32	39,8	38,2	38,9	48,4
LAVH			2	7,2	9,5	10	5	5	3	3	3	2	3	2	5,2	1,2
TAH	91,8	90,2	85	82,4	80,6	80	80	79	78	77	72	68	60,2	61,8	61,1	51,6

With initially increasing use of LAVH, the surgeons became more confident in the pre-operative assessment of operability by a history, bimanual examination, and pelvic sonar. Furthermore, they became more confident in operating "blind" (i.e. via the vaginal route), discovering that the laparoscopic component is most often superfluous. From Figure 8, we observe that when focus is directed towards VH, the need for laparoscopic assistance decreases as experience with VH is gained. This finding is opposed to other studies, which

have shown that if the focus is directed to LH, there is a resulting significant reduction in rates of VH to below 10%, without perceptible impact on AH rates [53].The advent of RH may also contribute to declines in VH rates [54]. In an evaluation of practice change in the wake of the introduction of RH Schmitt JJ *et al.* found that surgeons who would have performed VH in the pre-robotic era, now opt for RH instead [118].

6.2. Cost implications of performing LAVH as opposed to VH

During our overall study period (2001-2014), we introduced LAVH as an aid to achieve the vaginal removal of the uterus when there was an uncertainly of success of VH or if the pelvic anatomy needed to be restored before undertaking the VH. We observed a dramatic decrease in the use of LAVH as experience with VH was gained, especially towards the end of the study. Routine use of LAVH was never considered as a controversy in our unit, but rather as an additional tool in avoiding open AH. The benefits offered by VH are the same as LAVH; VH however is also faster, less costly, and associated with less scarring than LAVH [12-16].To establish LAVH as a routine procedure remains contentious, partly because of concerns about the cost of consumables needed to perform LAVH and the longer operating time of LAVH as opposed to VH.

6.2.1. Retrospective study: Cost analysis between VH and LAVH

In a retrospective cohort study, covering a period of two years (January 2015-December 2016), we evaluated hospital charges and costs for LAVH as compared to VH for a non-prolapse uterus in clinically similar groups of patients (see article 5). Both techniques offer the same benefits of shorter hospital stay, less analgesia needed, rapid mobilisation, and early hospital discharge. However, VH was found to be less costly, mainly due to its significantly reduced operative time, and the avoidance of the usage of consumables. The expensive laparoscopic devices and aforementioned extended operation times associated with LAVH make it the costlier procedure. The results of this study are in agreement with those of other investigations [13,67, 80, 119,120], which clearly demonstrate that VH is more cost effective while also providing the same advantages as LAVH. Key measures used in this study to assess the cost difference between the two procedures were related to operating time in theatre per minute, and the use of disposables during LAVH.

As mentioned, there are numerous studies that support VH in favour of other routes of hysterectomy based on the procedure's cost-effectiveness. In their comparison between costs and charges with three alternative techniques of hysterectomy (LAVH, AH, and VH), Dorsey *et al*. found that the mean total charges (facility charges plus professional fees) for the hospitalisation were much higher for LAVH as compared to VH ($p<0.001$) with the same clinical outcome [119].Similarly, a comparison of the costs and charges of LAVH, AH, and VH by Nehtat *et al.* that the mean cost of performing LAVH – as compared to VH – was significantly higher ($p< 0.05$) [120]. Through the eVALuate study, the vaginal approach was determined to be more cost-effective compared to the laparoscopic route, primarily due to the use of disposable instruments in laparoscopy [13]. Furthermore, Sculpher *et al.* demonstrated that LH cost an average of $780 more than VH, per patient [80]. With more than 500.000 hysterectomies performed annually in the United States, and more than 100.000 in the United Kingdom, the vaginal approach seems even more relevant in this time of economic strain [80].

Kovac *et al.* found that by using guidelines to assist clinical decision-making for hysterectomy, VH was determined to be feasible in 98.9% of the cases, with potential savings of 1.2 million USD for every 1000 hysterectomies performed vaginally, as well as a reduction of 20% in complications associated with hysterectomy[67].

In this study, LAVH took 32.7 minutes longer than VH ($p<0.001$).Considering the extra theatre time and the consumables used during LAVH, an estimated amount of 19306, 31 ZAR or 1532,24 USD more was needed to perform LAVH as opposed to VH for the same indication and uterine weigh (excluding the aforementioned professional fees). By performing VH instead of LAVH, a potential savings of 1.5 million USD could be obtained for every 1000 hysterectomies performed vaginally in SA.

During this study period, 470 hysterectomies were performed in our department. Out of these, 222 (47, 2%) underwent VH. 43 (9, 1%) of the VH have been accomplished with the aid of LAVH. This demonstrates that the rate of VH has been sustained and remains the same, with a ratio of 1:1 between TAH and VH observed by December 2016 (see article 5).

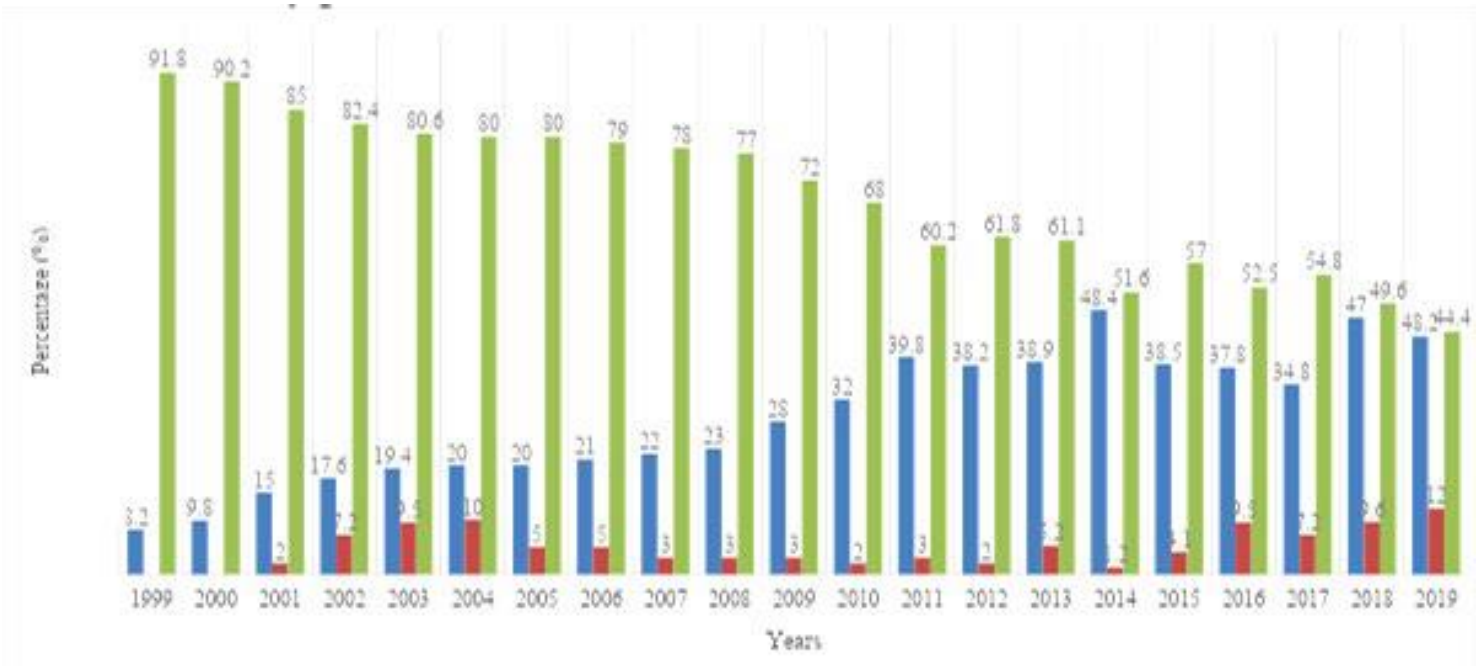
6.2.2. Prospective randomised control study between VH and LAVH

One of the objectives of this study was to evaluate the performance and outcomes of LAVH to VH in the absence of uterine prolapse in a randomised control trial. In this prospective randomisation, the differences in blood loss and cost between the two procedures were also assessed. The positive outcomes, as well as the high rates of VH of the retrospective studies (see articles 1, 5, 6), were also observed in the prospective study (see article 7).In this study, 720 women underwent hysterectomy for benign pathology during the study period at the CMJAH : 381 (51, 7%) underwent TAH, and 342 (48,2%) underwent VH [which
comprised of 286 (39.7%) VH and 76 (10.5%) LAVH](see Figure 7). A total of 227 patients, according to the protocol, were included in the prospective randomised study. 151patients underwent VH and 76 underwent LAVH, randomised on a 2:1 basis (knowing that the majority of hysterectomies performed by our unit are carried out vaginally). The results of this study demonstrated that the average hospital charges are significantly higher in LAVH as compared to VH. The main sources of the cost difference between LAVH and VH were related to the differences in operation time and the cost of consumables used during LAVH compared to VH, the latter of which requires no additional specific materials. An amount of 15 698,20 ZAR or 1145,85 USD more was needed to performed LAVH as opposed to VH for a non-prolapsed uterus. In this study, it was also demonstrated that there were no significant differences in blood loss between VH and LAVH as determined by the decrease in serum Hb levels in a day one following VH and LAVH. No patient required blood transfusion in our study groups, either for VH or LAVH. Our results are not in agreement with other studies, which showed that a significantly higher blood loss was observed during VH as compared to LAVH [73-75]. Our results are in agreement with by two large randomised prospective studies performed by Guo and Lee [76,77], which observed that there was no significant difference in blood loss between LAVH and VH.

The results of this study (see article 7) indicated that VH is a feasible option for cases with a non-prolapsed uterus and should be the preferred route of hysterectomy. Moreover, VH had a shorter operating time compared to LAVH, had minimal intra operative complications, was associated with no scarring, and was less costly as compared to LAVH. The results of this study are in support of other randomised studies which showed the same benefits of short hospital stay, rapid recovery and need of analgesia between VH and LAVH [12-16].

Regarding the rates of VH, this study demonstrates that has been sustained and remains the same as previously reported by this institution (see articles 5 and 6) with a ratio of 1:1 between TAH and VH observed by December 2019.

Figure 9: Percentage of hysterectomies performed per year over the whole study period.



6.2.3. Lack of training and experience as a cause of the global decrease in VH

Factors implicated in declining of VH include the lack of training and experience during residency, non-adherence to existing evidence-based guidelines for selecting appropriate candidates for VH, physician preferences, and a lack of patient knowledge about surgical options. In a survey performed by our unit (as part of this thesis) amongst practising gynaecologists in South Africa, the majority of the responders indicated lack of training and experience as the main obstacle in performing VH in private practice. The majority of the responders also found –once qualified–reluctant to change from open AH to the MIH (VH and LAVH) [113] (see article 4). This lack of training in VH has been raised by several authors as being an important factor, with lack of experience in vaginal surgery leading to gynaecologists having a dependence on the abdominal and/ or laparoscopic routes when contemplating hysterectomy [82-84].

Regarding training of VH during residency, it is important to distinguish between proficiency and exposure. In a survey about resident opinions on VH training performed in United States of America, 75% of the responders indicated that, in order to achieve proficiency during residency, more than 20 cases of VH are necessary [50]. The American College of Obstetrics and Gynaecology (ACOG) requests the number of 15 cases to be performed before completing the residency programme. In Nigeria, VH is underutilised as most centres hardly conduct more than five VHs in a year [52]. The situation in South Africa is similarly problematic because the South African College of Medicine (CMSA) requires only five VHs to be performed during a residency programme of four years. With these numbers, exposure is achieved but not proficiency. The future gynaecologist, not proficient to perform VH, may be inclined to perform hysterectomy by the abdominal route when it could be safely performed vaginally. This lack of proficiency also increases the likelihood of litigation should complications arise.

Despite these distinct benefits over LH (and RH), VH remains underutilised. Fortunately, there are considerable and rapidly increasing empirical examples based on randomised trials and large prospective national studies that have the capacity to direct opinion [11-16, 50]. Since we find ourselves in the era of minimally invasive surgery, we need to decide on a route of hysterectomy that best serves the patient. Our evidence suggests that the best way to perform a hysterectomy is the vaginal route, where feasible, but without undermining the role of LH. As a unit, we promote MIH, particularly in order to avoid the open AH; we support the emphasis of VH training, but are also able to perform LH when necessary.

As an academic unit responsible for training a large number of residents (±78 residents rotating through the unit), it can be difficult – if not impossible – to train them in LH. This procedure requires greater surgical expertise and has a steep learning curve due to the precision required in the laparoscopic skill set. VH, in comparison, is far easier to teach: it does not call for extra training, special skills, or complicated equipment. Furthermore, when considering the advantages of VH and LH, both offer the same benefits to the patient – but we must always bear in mind that VH is associated with fewer complications as compared to LH [17-19], and is much more cost effective.

CHAPTER 7: CONCLUSION

The results of this thesis, as well as the extensive review of the literature covered therein, demonstrate that when minimally invasive hysterectomy is feasible, VH should remain the treatment of choice for many gynaecological patients in whom hysterectomy is indicated (particularly for those with a non-prolapsed uterus). Conditions traditionally thought to be contraindications to VH –where the abdominal, laparoscopic, or robotic approach is often applied –should not preclude VH. This research has shown that such conditions can be treated successfully via the vaginal route. In doing so, patients are exposed to fewer surgical complications and a more rapid recovery. Furthermore, VH is demonstrably aless costly procedure in comparison to the other routes of hysterectomy.

In order to improve patient care, the high worldwide rates of AH should be reduced, in favour of VH. Through the introduction of formal clinical guidelines, a surgical tree algorithm, and a standardised surgical technique in our unit, we have shown that this is possible: an increase in the number of VHs performed was observed, as well as a decrease in the rate of open AH. With the establishment of standardised selection criteria and surgical guidelines, we have created an opportunity for residents to acquire, improve, and maintain the skills required to perform VH.

In conclusion, VH has been demonstrated to be a safe and cost-effective procedure that should be offered to a large group of appropriately selected women. This study has shown that it is possible to shift the ratio of AH to VH. We believe that if this approach were to be implemented in dedicated institutions worldwide, a decrease in the global AH rate would be observed and further positive outcomes in patients undergoing hysterectomy. However, such change requires greater efforts to be directed towards teaching the technique of VH during residency. It is here that governing bodies (such as the ISGE, ACOG, AAGL, and RCOG) have the greatest role to play.

CHAPTER 8: ETHICS APPROVAL

The study has been approved by the Wits Human Research Ethics committee, with a clearance certificate number of M150462 (Appendix 8). Approval has been obtained from the CEO of CMJAH (Appendix 9). National Health Laboratory services permission will be obtained to access the histology results.

8.1 Timing

	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Literature Review	**COMPLETED**										
Data Collection											
Data Analysis											
Write-up											
Supervisor Input											

8.2 Funding

The thesis will be self-funded, including stationery, photocopying, printing and binding, transport at an estimated R2 000-00.

8.3 Limitations

Component 1 and 2: The study is retrospective. There is a possibility of missing data and lost files.

APPENDIX 1: VAGINAL HYSTERECTOMY FOR NON-PROLAPSED UTERUS – INNOVATIVE TECHNIQUE USED BY THE UNIT

The ten steps vaginal hysterectomy for non-prolapse uterus, introduced into the unit by the head of the unit (PI). This is a standardized surgical technique used by the unit since 2001, the beginning of the study. This description will stand you in good stead whatever the clinical diagnosis or variation in anatomy. Improvisation is not an option in vaginal surgery. It is vital to perform each step of surgery in the same way and in the same order.

1. Positioning the patient

After appropriate general or regional (spinal) anaesthesia is completed, the patient is placed in the dorsal lithotomy position with her feet in stirrups. The patient buttocks should extend slightly over the edge of the table so that the posterior retractor can be placed easily. In this position the thighs are somewhat abducted and the hips flexed. Excessive flexion and abduction of the thighs should be avoided in normal circumstances, as this can lead to position-induce nerve injuries. The lateral aspects of the legs should be clear of the stirrups to avoid pressure on the peroneal nerve (Fig1a).

The urinary bladder is then emptied with a metallic urinary catheter and the vaginal area is prepped in a normal fashion. A careful and completed bimanual examination must then be performed to confirm the degree of uterine descent and the width of the vaginal outlet. This step may not be omitted as it can give valuable information about previously unrecognized pelvic pathology, as well as the best operative approach to use and the degree of difficulty to be expected.

The cervix is exposed by placing a weighted posterior retractor or the blade of the Auvard speculum. A small right angle retractor (Wertheim angle retractor) may be used to elevate the anterior vaginal wall. Two vulsellums are then utilized to grasp the anterior and posterior lips of the cervix and pull them into the vaginal introitus. The Vulsellum placed on the anterior lip of the cervix, upside down, so that instead the instrument being concave upwards, it is concave downwards. The second vulsellum is placed on the posterior lip of the cervix with the instrument being concave upwards. I found it to be much easier to manipulate the cervix this way and helps with the orientation during the procedure. Additionally, the instruments do not seen to come off as easily when using this method. While traction of the

cervix downward is applied, massaging the uterosacral and cardinal ligaments bilaterally, especially on the left, may facilitate further descend. This procedure should be performed as follows:

Holding the vulsellums with the left hand and pulling it slightly to the patient's right, the index finger of the right hand is used to massage the left paracervical tissues (uterosacral/ cardinal ligaments) starting from forwards and going backwards towards the rectum. This manoeuvre has been described by J.L Cohen [121] and I found it very useful to achieve further descent when operating on non prolapse uterus, as it allows easier access.

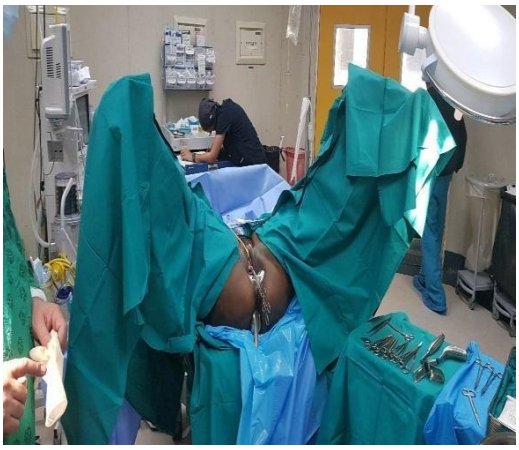


Fig. 1a: Positioning the patient.

Fig 1b: Super flexion position

Obesity should not be considered as a contraindication to VH. Obese women who present with a BMI >35 (or morbidly obese women) may benefit from VH as they avoid the high risk of venous thrombo-embolism, wound infection and dehiscence, and respiratory compromise associated with the open total abdominal hysterectomy. It is advisable to apply a super flexion position— in which the patient lies on the table in dorsal position with buttocks protruding beyond the edge of the table with both thighs abducted and fully flexed (Fig.1b). Anatomically, this position makes the uterus descend downward and fall backward, bringing the cervix closer to introitus. This may also facilitate bilateral salpingo-oophorectomy or a cystectomy where this is needed [122].

1. Incision of the vaginal wall

While downward traction is applied with the vulsellums, a circular incision around the cervico-vaginal junction is performed. We disagree with Michael Stark that the incision around the cervix should be done around 5mm above the external os [123]. The incision in

the vaginal mucosa should start anteriorly and extend around posteriorly to the cervix. The level of the incision is critical to finding the correct plane of dissection between the bladder and lower uterine segment. The point of attachment of vaginal mucosa to the cervix can be demonstrated by moving the cervix up and down several times. The incision should be made at the border between the smooth cervical mucosa and the vaginal rugae (Fig 2a,2b).

An incision above the border of the cervix and vaginal rugae can lead to bladder injury and unnecessary bleeding, whereas if the incision is below the border, incision of the cervix it may cause bleeding. It is important the incision to be deep enough reaching the pubo-cervical fascia which appears at this level as a white or pale grey area. The vaginal mucosa is circumferentially pushed up, away from the incision, with the use of a swab-covered index finger. This is done all the way up to the peritoneal vesico-uterine fold anteriorly and posteriorly as far away up to the insertion of utero sacral ligament to the cervix.

The blade of the Wertheim angle retractor is placed under the vaginal mucosa and the bladder. Then, with strong traction on the cervical vulsellums downward and counter traction with the retractor lifting up the anterior vaginal wall, the proper plane of dissection between the bladder and the cervix is found (2b). This manoeuver aids to identify the peritoneal vesico-uterine fold or anterior peritoneum, which appears as a pearly-white transverse line across the lower uterine segment lying on the wide V-shaped, shiny serosal surface of the uterus.

Circular incision around cervico-vaginal junction had been proposed also by Sheth [124]. Heaney and Green- Armytage described the same steps in support of our technique long before him [125,126]. We prefer opening the anterior and posterior peritoneum before clamping and cutting the uterosacral and cardinal ligaments. This is opposed to the technique described first by J.Cohen [121], and followed by others [124-128]who proposed routine opening of the vesico-uterine peritoneum after clamping and cutting the uterosacral and cardinal ligaments or the uterine vessel. In some circumstances when is not feasible to enter the anterior peritoneum is worthy to detached the uterosacral and cardinal ligaments from their attachment, once the bladder has been mobilized. This will facilitate further descent of the uterus and assist with the identification and opening of the bladder peritoneum.

Figure 2a: strong downward traction is applied to the cervix with the valsulum and counter traction upwards with the blade of the Wertheim angle retractor; the cervico-vaginal junction is identified.

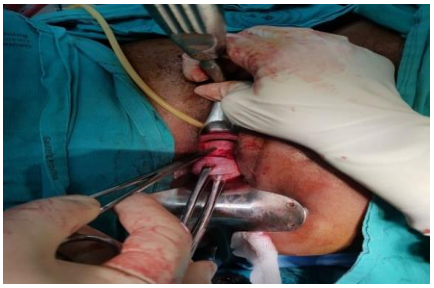


Figure 2b: A circumferential cervical incision is accomplished

2. Opening posterior peritoneum

We advise that it is preferred to open the posterior peritoneum first. The vulsellums holding the cervix are pulled upwards by the assistant. The peritoneum between the two utero-sacral ligaments is grasped with artery forceps and opened with curved Mayo scissors. The scissors are then introduced into the Pouch of Douglas cavity. With the blades of the scissors inside the peritoneal cavity, the scissors are opened and the blades withdrawn in the opened position so that the peritoneum is being cut by the by the back of the blades of the open pair of scissors, as they are being withdrawn. In order to do this, it is necessary to hold the handles of the scissors with both hands(Fig3a). In this way, the peritoneum is opened until the insertions of the uterosacral ligaments are bilaterally exposed.

With the index finger into the Pouch of Douglas cavity, the posterior aspect of the uterus is palpated. Fibroids or adhesions may be identified at this point, together with the size and mobility of the uterus. The blade of the Auvard forceps or Sims speculum, is introduced into the peritoneal space (pouch of Douglas). A large swab can be inserted into the posterior pouch preventing small bowel and omentum entering the operating field. (Fig 3b)

Additionally, It is preferable to open the posterior peritoneum first because in some cases, such as previous caesarean sections or cases of anterior fibroids, the anterior peritoneum may be difficult to be open. In such circumstances, the index finger is introduced behind the uterus over the fundus of the uterus and the vesico-uterine peritoneum is identified and opened. This approach is supported as well by others [123-128].

Figure 3a: The posterior peritoneum is opened.

Figure 3b: The blade of the Sims speculum or weighted retractor is the place in the posterior cul-de-sac.

3. Detaching the bladder from the uterus

With the blade the Wertheim angle retractor under the vaginal mucosa and bladder, the bladder is pushed-up close to the uterus. As downward traction is applied with the vulsellums, and counter traction upwards with the blade of the Wertheim angle, the bladder will be separated from the uterus until the utero-vesical fold is exposed and the anterior peritoneum is identified. Exposure of the anterior peritoneal (utero-vesical) pouch is the most crucial step during VH. This is recognised as a white or pale area owing to the double layer of peritoneum. Confirmation that this is the peritoneal sac can be obtained by picking up the anterior layer with forceps (Fig4a). The peritoneum is grasped with artery forceps and opened

with curved Mayo scissors (Fig4b). The blade of the Wertheim angle retractor is placed into the peritoneal cavity, separating the bladder from the uterus.

In our technique, entrance into the anterior and posterior cul-de-sac is established before clamping and cutting the uterosacral/cardinal ligaments and definitely before clamping and cutting the uterine vessels. This facilitates the successful vaginal removal of the non-prolapsed uterus and is associated with less bleeding and the prevention of potential injury to the bladder and/or ureters anteriorly, as well as to the rectum and small bowel posteriorly.

As mentioned above, this is in disagreement with J.Cohen [121] and others [124-127] who also stress the importance of getting into the two spaces routinely after clamping and cutting the uterosacral/cardinal ligaments and uterine vessels. The traditional teaching during open abdominal or laparoscopic hysterectomy is to reflect and/open the vesico uterine peritoneum before clamping and cutting the uterine vessels in order to avoid damaging bladder and ureters anterior.

Figure 4a: The peritoneum is grasped with artery forceps.

Figure 4b: Opened with curved Mayo scissors.

In patients with previous caesarean sections or who present with previous inflammatory diseases or endometriosis, this pouch may be obliterated or difficult to define. In such circumstances, it is not advisable to open the anterior pouch, due to the risk of injury to the bladder. There are two safety measures that may be used as alternatives; insertion of the bladder sound or metallic catheter that is safe to proceed, or waiting until the pouch of

Douglas is open and the index finger can be passed over the uterine fundus or broad ligament to define the anterior pouch. Although not routinely in such circumstances we detaching the uterosacral/ cardinal ligaments of their attachments, achieving further descent of the uterus that may make easier the entry into the anterior peritoneal cavity. If we are still not able to enter the space, we advise to proceed to LAVH.

Sheth SS [129], recommends instead to proceed to laparoscopy, to make use of the uterocervical broad ligament space. This space is bounded by a tangential line joining the maximally bulging point on the uterine body and cervix. The uterocervical border with the isthmic notch as its centre has two third of the space medially and one third laterally. The leaves of the broad ligament are well separated close to uterocervical border and run closer for some distance before funning out laterally. Thus, separation of the two leaves close to uterocervical border is easy. The space varies with the uterine size but on average measures 2,5 X2,0 cm and contains loose areolar tissue, lymphatics and the uterine vessels at the point of entry into the uterine wall. The ureter is away.

The surgical technique had been described as follow: During VH, after vaginal mucosa is incised and push away with the bladder with the assistance of Wertheim angle, the dissection is made laterally, first by scissor between the cervix and the bladder to enter the uterocervical space making room for the finger to follow, then insinuating upward and laterally beyond the lateral uterocervical border to enter into the continuing space between the two leaves of the broad ligament (Fig4c). The space is thus entered by sharp and blunt dissection and is gradually enlarge by the finger. After reaching the area between the uterocervical surface posteriorly and the bladder anteriorly and using gentle traction medially with Babcock forceps on the free bladder, assisted by sharp and blunt dissection the bladder is separated from the uterocervical surface.

Entering the utero cervical broad ligament space (S Sheth)

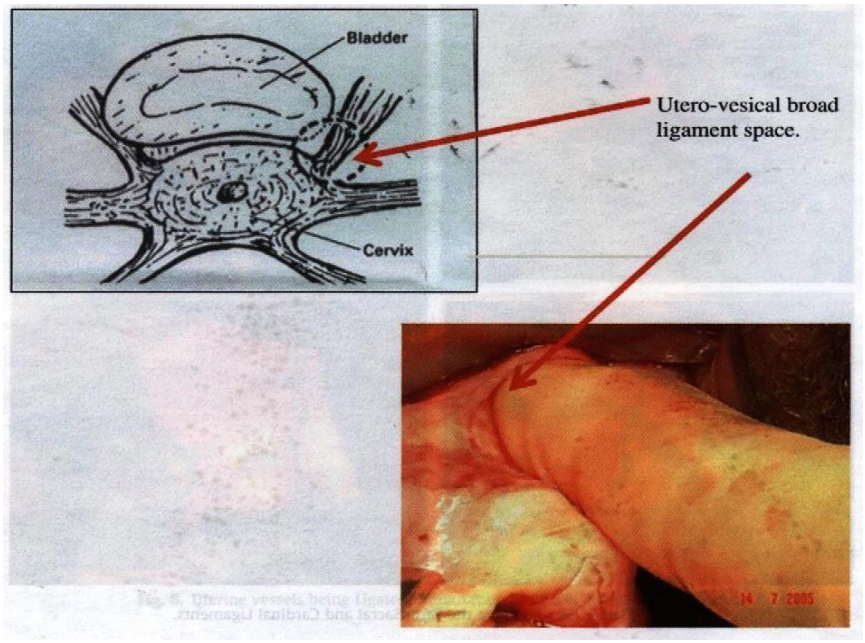


Figure 4c: Detaching the bladder from the uterus.

5. Dissection of the utero-sacral ligaments (USLs) and cardinal ligaments (CLs)

The utero-sacral ligaments (USLs) and the cardinal ligaments (CLs) provide apical support of the upper vagina and the uterus. The USLs, from their attachments to the dorsal margin of uterine cervix and/ or to the upper third of the posterior vaginal wall, pass backwards and upwards to reach the sacrum (S2-S4 region). The CLs (also referred to as Mackernodt's ligaments, lateral cervical ligaments or transverse cervical ligaments) are condensations of endo-pelvic fascia and from their attachments to the lateral upper part of the vagina and cervix are spread outwards in a fan-shaped manner to the bony pelvis. Although both ligaments are located in different anatomical planes and directions, they are clamped together. This is done in a specific way: the cervix is pulled upwards and laterally with the vulsellums and the uterus is contra-rotated. A curved Maingot clump is placed in the posterior cul de sac with one blade underneath the USL/CLs complex and the opposite blade over the USL/CLs complex. The clamp is placed perpendicular to the long axis of the uterus next to the uterine cervix so that some tissue of the cervix is included in the clamp. It is important that the clamp is not placed laterally to the cervix because the cardinal and uterosacral ligaments lies at the lower end of the broad ligament below the uterine artery and are pierced by the ureter, which lies in ureteric canal lateral to the artery.

Both anatomical structures (USL/CLs) are cut and ligated with 0 or 2-0 delayed absorbable suture, using a full-length suture with the needle attached(Fig5a,b,c,d). These sutures are not

cut but clipped to the covering drapes. The procedure is repeated on the contralateral side (Fig5e, f). This manoeuvre facilitates further descent of the uterus. These two sutures, with the needles attached will be used for closure of the vault to support the vault and avoid vault prolapse.

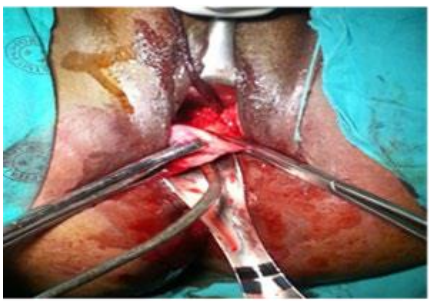


Figure 5a

Figure 5b

Figure 5a,b: Once the bladder is mobilised, a curved Maingot clamps the US and CLs. The clamp is placed perpendicular to the long axis of the uterus next to the uterine cervix so that some tissue of the cervix is included in the clamp and cut.

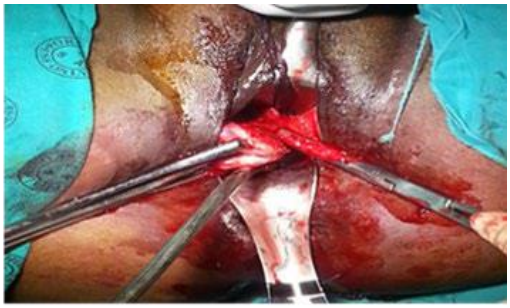


Figure 5c

Figure 5d

Figure 5c, d: Both anatomical structures (USL/CLs) are ligated with 0 or 2-0 delayed absorbable suture, using a full-length suture with the needle attached. These sutures are not cut but clipped to the covering drapes and will be used for closure of the vault to support the vault and avoid vault prolapse.

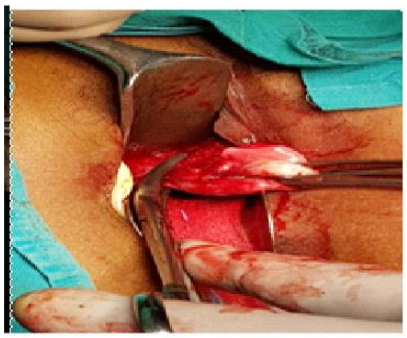


Figure 5e

Figure 5f

Figure 5e, f: The procedure is repeated on the contralateral side.

6. Cutting and legating the uterine arteries

Both uterine arteries are clamped, cut and ligated. The uterine vessel pedicle, which contains the uterine artery and vein, and the broad ligament peritoneum anterior and posterior to these vessels, is clamped, cut, and ligated with a no. 0 or 2-0 delayed absorbable suture(Fig6a,b,c,d).

Routine opening of the vesico-uterine peritoneum after clamping the uterine vessels as recommended by Stark [123], and sometimes by others [124,127,128] may lead to the injury of the bladder and ureters.

Routine opening the peritoneum after clamping the uterine vessels should be avoided. In rare circumstances, it is advised, when the anterior peritoneal site cannot be reach earlier, careful severance of the uterosacral, cardinal ligaments, vesico-uterine ligaments and uterine vessels bilaterally will lead to the anterior peritoneal reflection, provided angles of the bladder and the bladder are retracted laterally and superiorly away from the uterus with the Wertheim angle retractor placed between the uterocervical surface and the bladder [130-134]

We partially agree with the above statement; in situations where the anterior pouch cannot be entered then incised the uterosacral/ cardinal ligaments may achieve further descend of the uterus making the entrance into the anterior and posterior cul de sac feasible. If no entrance to the above spaces can be achieved, further steps to reach the uterine vessels vaginally have also been suggested [130,134-136]. These steps however should not be taken routinely, as the risk of injury to the bladder and ureters is very high. In this situation we recommend the vaginal approach to be abandoned and to rather undertake LAVH in order to assess and correct the anatomy, thus facilitating completion of the hysterectomy vaginally or laparoscopically.

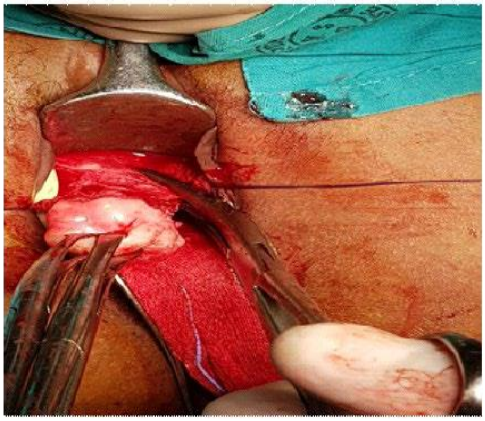


Figure 6a

Figure 6b

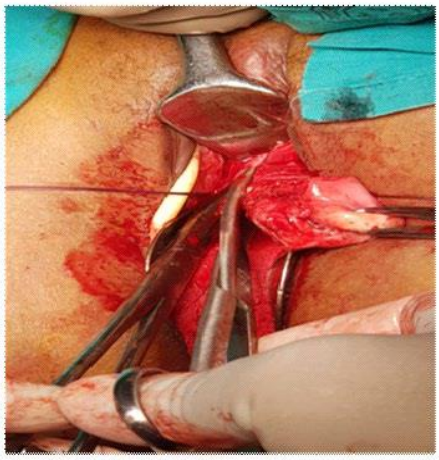


Figure 6c

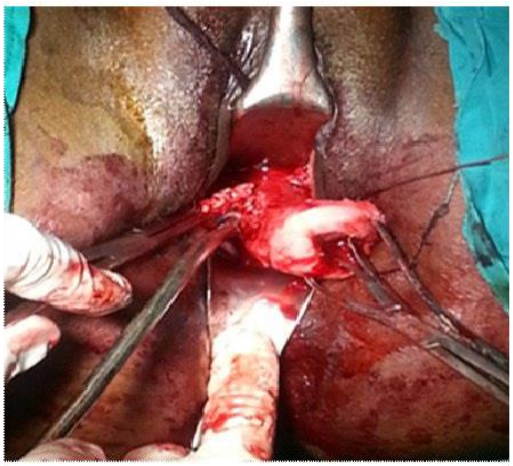


Figure 6d

Figure 6a,b,c,d: The uterine vessel pedicle, which contains the uterine artery and vein, and the broad ligament peritoneum anterior and posterior to these vessels, is clamped, cut, and ligated with a no. 0 or 2-0 delayed absorbable suture.

7. Dissection of the upper part of the uterine support

The remaining portion of the broad ligament attachment to the uterus contains the round and ovarian ligaments, the fallopian tube and the blood vessels and this is then clamped, cut and ligated bilaterally; the maingot clamp should be placed as close to the uterine fundus as possible(7a,b,c,d). The uterus is then detached. The pedicles are tied separately and should not be tied together. We disagree with Stark [123] and Bina [130]who advised to ligate these pedicles to each another. Tying the pedicles together will bring the ovaries into the Pouch of Douglas, which may lead to severe deep dyspareunia post-operatively.

If the adnexa are to be removed, traction is placed on the ovary by grasping it with a Babcock clamp. A Maingot clump is placed across the infundibulo-pelvic ligaments, and the ovaries and tubes are excised. Both a suture tie and a transfixion suture ligature are place on these pedicles.

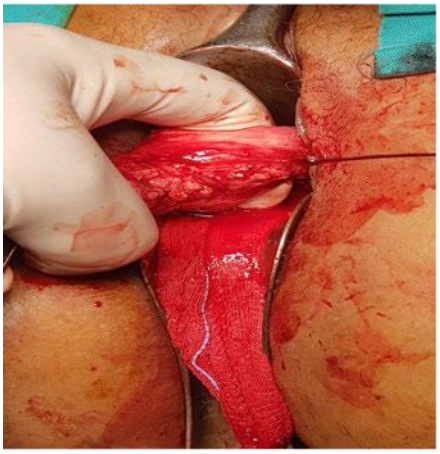


Figure 7a

Figure 7b

Figure 7c

Figure 7d

Figure 7 a,b,c,d : The three elements (round ligament, fallopian tube and ovarian ligament) bilaterally can be taken in the same clamp, divided at sufficient distance from the clamp, closed to the uterine fundus. The pedicles are tied separately and should not be tied together.

8. Closure of the peritoneum

Once satisfied with the haemostasis, closure of the peritoneum is performed with no. 0 or 2-0 delayed absorbable suture. In order to find the posterior peritoneum, the swab-holding forceps is introduced into the peritoneal cavity and withdrawn by sweeping the swab out posteriorly. This literally pushes out the posterior peritoneum and presents it into the operator's field of vision. The posterior peritoneum is grasped with a pair of straight artery

forceps. Once this is done a new swab holding forceps is introduced into the peritoneal cavity and withdrawn by sweeping the swab out anteriorly, having the same effect as was noted with the posterior peritoneum.

The closure of the peritoneum is carried out with a purse-string suture. The suture commences on the anterior peritoneal edge. Pick up the peritoneum between the pedicles on the left side and bring the suture through the stump of the right uterosacral ligament. Pick up the posterior peritoneum of the cul de sac, and continue upwards through the stump of the opposite uterosacral ligament. Pick up the peritoneum between the pedicles on the opposite side and then bring the suture through the remaining anterior peritoneum. When this suture is tied, the pelvis is re-peritonealized thus leaving the USL/CLs stumps outside the abdominal cavity (8a,b,c,d). Closure of the peritoneum is recommended by our unit as this will prevent prolapse of the fallopian tubes, which can be a cause of severe pain post-operatively. May also prevents bowel evisceration and posterior enterocoele formation postoperatively, after the VH. Searching the literature there is insufficient data to recommend for or against adding peritoneal closure when closing the vaginal cuff [131-133]

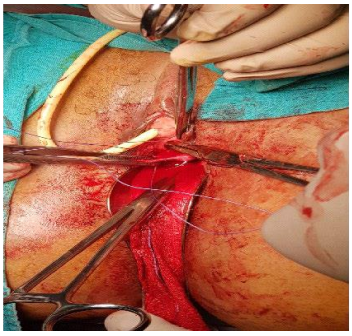


Figure 8a

Figure 8b

Figure8c

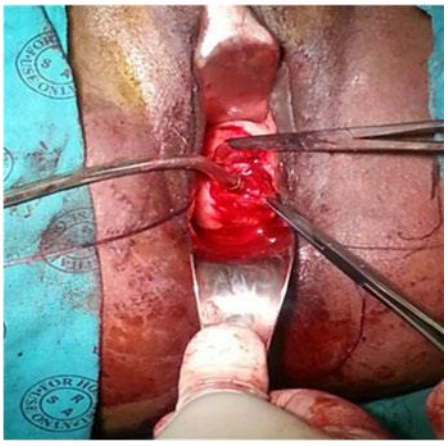


Figure 8d

Figure 8 a,b,c,d: The closure of the peritoneum is carried out with a purse-string suture. The suture commences on the anterior peritoneal edge (8a). Pick up the peritoneum between the pedicles on the left side and bring the suture through the stump of the right uterosacral ligament (8b.). Pick up the posterior peritoneum of the cul de sac, and continue upwards through the stump of the opposite uterosacral ligament. Pick up the peritoneum between the pedicles on the opposite side and then bring the suture through the remaining anterior peritoneum (8c). When this suture is tied, the pelvis is re-peritonealized thus leaving the USL/CLs stumps outside the abdominal cavity (8d).

9. Closure of the vaginal vault

Each angle is closed separately with the stitch and needle held at the US/CLs complex on each side. Placating the pedicles to the lateral vaginal mucosa offers additional support to the vaginal vault preventing vault prolapse (Fig 9a,b,c,d,e,f). Once the angles are secured, the closure of the vault is carried out with continuous interlocking sutures with the same stitch bilaterally in a horizontal manner. Horizontal closure is preferred to vertical closure as is associated with less vaginal constriction and deep dyspareunia postoperatively. The upper vagina is the roomiest part of the vagina. The deepest point of the vagina is the posterior vaginal fornix. Because the cervix in the non-prolapsed uterus comes through the anterior vaginal wall, the depth of the vagina is not affected, and there is not a need of additional vault suspension.

Searching the literature there is not sufficient data to support vertical or horizontal closure of the vaginal cuff [133-136]. When horizontal closure compare to vertical closure, there were no dyspareunia or prolapse reported. Closure technique did not demonstrate any difference in operative time, blood transfusion or cuff cellulitis [133,134].

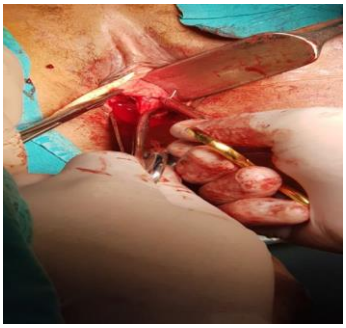


Figure 9a

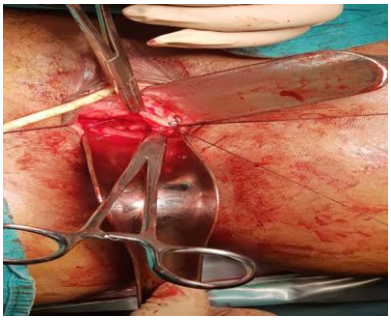


Figure 9b

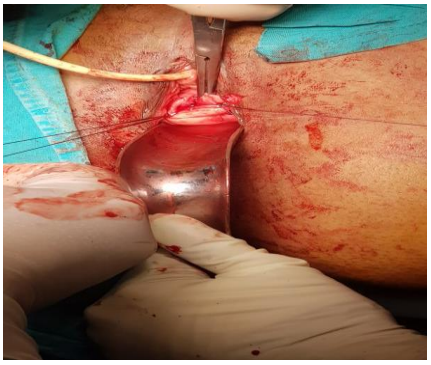


Figure 9c

Figure 9d

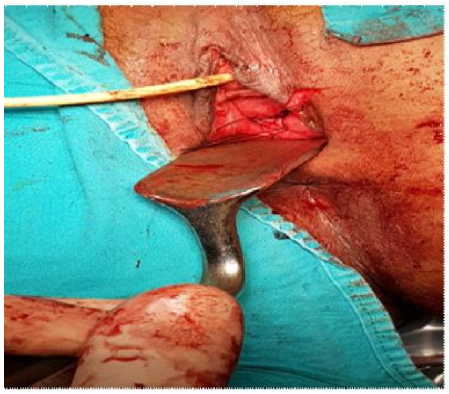


Figure 9e

Figure 9f

Figure 9a,c : Each angle is closed separately with the stitch and needle held at the US/CLs complex on each side.

Figure b,d,e,f: Once the angles are secured, the closure of the vault is carried out with continuous interlocking sutures with the same stitch bilaterally in a horizontal manner.

10. A urine catheter and vaginal plug are inserted, and removed the following day.

There is not sufficient evidence supporting routine vaginal packing following vaginal hysterectomy. Three RCTs found no apparent net benefits to vaginal packing for postoperative pain, satisfaction, bleeding or infections. In addition, vaginal packing did not have an effect on the presence of a cuff haematoma six weeks after the surgery [137-139]. The recommendation against routine postoperative packing reach grade 1B recommendations indicating that the risks of postoperative vaginal packing generally outweigh the benefits for most patients. In cases that vaginal packing is chosen, indwelling catheter must be inserted in order to allow urine drainage and avoid postoperative urine retention

We recommend early removal of the bladder catheter to avoid febrile morbidity, facilitate faster mobilization, and decrease length of hospital stay. However, there is not sufficient evidence supporting prolong catheterization. [140-143].

Figure 10a

Figure 10b

Figure 10: Control haemostasis (10a). Urine catheter and vaginal plug are inserted (10b).

Panel 1: Vaginal Hysterectomy Inclusion and Exclusion Criteria

Inclusion Criteria

a. Uterine size not exceeding an equivalent 14-week pregnant uterus on clinical examination.
b. Uterine size not exceeding 14 cm in length and 9 cm in width on ultrasound examination, or uterine weight of 360g or less.
c. Pathology confined to the uterus.
d. Women with a non-prolapsed uterus, nulliparous women, women with previous pelvic surgery, women with previous caesarean section(s), women with cervical dysplasia or pre-malignant conditions, women with endometrial hyperplasia (with or without atypia), women with chronic pelvic pain, and women with fibroid uteri up to 14 weeks in size may be treated with VH.
e. Prophylactic salpingo-oophorectomy should not be a contraindication

Exclusion Criteria

a. Malignancy
b. Virginity
c. Enlarged uterus (more than 14 weeks on clinical examination, or more than 360g on ultrasound)
d. Uterus not accessible vaginally
e. Inexperienced surgeon (seek help or refer patient)

Instrumentation:

Instruments needed for vaginal hysterectomy:

- Metallic urinary catheter
- Auvard weighted vaginal speculum
- Wertheim angle retractor
- 2 multiple toothed vulsellums
- #15 scalpel
- 2 Maingot hysterectomy clamps
- A curve Mayo scissor or Metzenbaum scissor
- A needle holder
- Suture material. We prefer MO5 needle ½ circle with 0 or 2.0 delayed absorbable suture attached
- Artery forceps
- Vaginal plug
- Indwelling Foley catheter (post-operative)

APPENDIX 2: LAVH PROCEDURE

Prior to proceeding to vaginal hysterectomy, a laparoscopic assessment of the pelvis and pelvic organs is performed. The Laparoscopic component of VH includes the assessment of the pelvic organs, release of adhesions, treatment of endometriosis where necessary, and freeing the adnexae laparoscopically. The laparoscopic component is carried out up to the opening of vesico-uterine peritoneum.

The steps are as follows:

1. Preparation of the patient

The patient is placed in dorsal lithotomy position. The arms are tucked at the side and a foam mattress is situated directly under the patient to prevent sliding during steep Trendelenburg.

2. The bladder is emptied with metallic catheter or a Foleys catheter is inserted into the bladder and filled with 10ml of saline.
3. Insertion of uterine manipulator

Uterine manipulator is important to facilitate movements of the uterus during the procedure.

4. Abdominal entry and trocar placement

A 10mm skin incision is made at the deepest part of the umbilicus using a number 15 blade. By elevating the abdominal wall a trocar /cannula with a 10mm telescope 0˚ with a camera attached to it is introduced into the abdomen (visual guided entry).
The insufflator is attached to the cannula and pneumoperitoneum is obtained (intra-abdominal pressure always maintained to 15mm Hg during the procedure).

Two 5mm incisions are performed, one suprapubically and the other one medial to anterior superior iliac spine on the left. 5mm trocars under direct vision are inserted to facilitate the operation. If needed, a third 5mm incision is performed on the left 8cm away from the midline at the edges of rectus muscle where the third trocar can be inserted if needed.

5. The round ligaments bilaterally are transected with the harmonic scalpel or a bipolar grasper and scissor. If the ovaries are to be removed, then the ovaries are pulled medially and the infundibulo-pelvic ligament is transected close to the ovary. If the ovaries are

going to be preserved, then the ovarian ligament, the tube and the round ligament are transected.

6. Mobilise the bladder. After transecting the round ligaments bilaterally, the anterior and posterior leaves of the broad ligament are separated. The vesico-uterine peritoneum from one round ligament to the other is transected and the vesico uterine peritoneal fold is identified. It is important that the uterine manipulator to be pushed upwards towards the uterus during the dissection of the bladder, as this facilitates the opening of the vesico uterine peritoneum.

At this point the rest of the operation is then undertaken vaginally (Appendix 1). After closure of the vaginal vault and peritoneum, laparoscopy is performed to assess and secure haemostasis. It is also crucial to assess for any complications of the procedure and to wash out blood clots and debris. All patients receive prophylactic antibiotics intra-operatively.

APPENDIX 3: PATIENT INFORMATION SHEET

Hello,

I am Dr Andreas Chrysostomou, a senior doctor in the Department of Obstetrics and Gynaecology at the Johannesburg Hospital. We have found that most women, who need to have their wombs removed (hysterectomy) for gynaecological problems, have the operation done through a cut (incision) through their tummy (abdominal) wall. This is called an abdominal hysterectomy.

In some cases, the womb can be removed from below (through the vagina without the cut in tummy). This is called a vaginal hysterectomy. This type of operation results in less pain afterwards and allows you to go home and back to normal activities much sooner.

Laparoscopic Hysterectomy (LAVH) sometimes is needed to help with the removal of your womb (uterus) from below (through the vagina without the cut in the tummy)

At the beginning of Laparoscopy, a small instrument (Laparoscope with a camera attached) is introduced through a tiny incision (1cm) below your belly button (umbilicus) and look at the female organs as with a telescope.

To perform the surgery, the doctor does the first part of the surgery using Laparoscopic instruments. To do so, the doctor needs additional 2 to 3 small incisions in the abdomen (tummy), half centimetres each. With the instruments passing through these small incisions (holes) the surgeon frees the upper part of the uterus from the surrounding tissues. Once this is done, the doctor makes a cut around the vagina to remove the uterus (womb). After the uterus (womb) is removed the doctor sews the top of the vaginal closed so that the hole does not exist between the vagina and the abdomen.

This entire procedure (laparoscope+ vagina hysterectomy) takes about one to one and half hour to perform. The risks include possible injury to tissues or structures in the tummy wall or below the tummy wall. These possible risks are:

1. Vessel injury may involve inferior epigastric or rarely larger vessels in the pelvis.

2. Bladder injury is avoided by catheterising the patient (putting urine pipe). Ureteric injury may occur during operative laparoscopy.

3. Intestinal injury. Uncommon but may occur if adhesions are present. Avoided by careful assessment and introduction of Veres needle and cannula (putting gas in the tummy).

4. General anaesthetic risk is present to the extent that it could apply to any patient receiving general anaesthetic. General anaesthesia would usually be used for hysterectomy in any case.

The above complications are uncommon and occur with less frequency as the experience of the surgeon increases.

If you have been booked to have an abdominal hysterectomy we would like you to consider having the laparoscopy to assess whether your operation can be done from below (vaginal hysterectomy). Although we cannot guarantee that you may not still need the abdominal hysterectomy, it will give you a good chance of having the vaginal hysterectomy with the advantages of less post operation pain and earlier return to normal activities.

Should you like to take part in this research study, any questions which may arise will be fully answered. Taking part in this study is completely voluntary and you may decline to take part or change your mind at any time before the operation.

If you decline or change your mind, you do not have to give any reasons for your decision and it will not affect your treatment in any way.

All the information you give us will be kept confidential and your name and hospital number will not be known to anyone except the medical and nursing staff taking care of you.

If you agree to participate in the study we will ask you to sign the informed consent form to have a laparoscopy and a vaginal or an abdominal hysterectomy.

If you would like to obtain more information about the study or ask any questions at all please contact me, Dr Andreas Chrysostomou in the ward (ward 196) or through the Sister in Charge of the ward 196 (Sr. Jane Ndzebo). My cell phone number is 083 324 4122; you may phone me at any time of the day or night.

We hope the study will benefit patients in the future by allowing us to do more vaginal hysterectomies instead of abdominal hysterectomy.

Thank you for considering participation in the study.

Patient signature

Doctor Signature

APPENDIX 4: INFORMED CONSENT FORM

I .....understand the written explanation given to me and I *(name of patient)*understand the complications which may occur during the operation.
I .....consent for Laparoscopy Assisted Vaginal Hysterectomy or *(name of patient)*Vaginal Hysterectomy.

I am aware that if necessary instead abdominal hysterectomy will be performed on me.

I understand that I have the right to refuse this treatment and refusal will not affect my treatment in any way.

I have discussed the matter with Dr Chrysostomou and I have understood what he was explaining.
Patient name: ……
Signature……..
Date:.....Time

APPENDIX 5:DATA SHEET COMPONENT 1

Patient Study number

Patient Characteristics

Age _____

Parity _____ Gravidity _____

Indication for Hysterectomy _____

_____

Uterine weight _ grams

Short term clinical outcomes

Length of hospital stay _____ Days

Need for blood transfusion Y/N

Pre-operativeHb _____ g/dL

Post-operativeHb _____ g/dL

Need for reoperation Y/N

Operative complications

Haemorrhage Y/N

Need for blood transfusion Y/N

Bowel injury Y/N

Bladder injury Y/N

APPENDIX 91: DATA SHEET COMPONENT

Patient Study number _____

Patient Characteristics

Age _____

Parity _____ Gravidity _____

Indication for Hysterectomy _____

_____

Uterine weight _ Grams

Short term clinical outcomes

Length of hospital stay _____ days

Need for blood transfusion Y/N

Pre-operativeHb _____ g/dL

Post-operativeHb _____ g/dL

Need for reoperation Y/N

Operativecomplications

Haemorrhage Y/N

Need for blood transfusion Y/N

Bowel injury Y/N

Bladder injury Y/N

APPENDIX 92: DATA SHEET COMPONENT

Patient Study number _____

Patient Characteristics

Age _____

Gravidit _____

Parity _____ y _

Indication for Hysterectomy _____

_____

Uterine weight _ Grams BMI (kg/m2) _____

Race B/W/I/C

Short term clinical outcomes

Length of hospital stay _____ days

Need for blood transfusion Y/N

Pre-operativeHb _____ g/dL

_____

Post-operativeHb _ g/dL

Need for reoperation Y/N

Need for

analgesia: Number Pethidine doses required: _____

Operative complications

Haemorrhage Y/N

Need for blood transfusion Y/N

Bowel injury Y/N

Bladder injury Y/N

Conversion to AH Y/N

Operative time taken _____ minutes

APPENDIX 8: ETHICAL CLEARANCE CERTIFICATE

R14/49 Dr Andreas Chrysostomou

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150462

NAME: (Principal Investigator)	Dr Andreas Chrysostomou
DEPARTMENT:	Obstetrics and Gynaecology Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	The Preferred Route of Hysterectomy: A Continuing Conudrum
DATE CONSIDERED:	24/04/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Franco Guidozzi

APPROVED BY: _____

Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 14/10/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

_____ _____

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 9: CMJAH CEO APPROVAL OF STUDY

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Mr. J. Maepa
Office of the Clinical Director
Tell: (011): 488-3365
Fax: (011): 488-3753
12 June 2015

Dr. A. Chrysostomou
CMJAH

Dr. A. Chrysostomou

STUDY TITLE: The Preferred Route oh Hysterectomy: A continuing Conundrum

Permission to conduct the above mentioned study is provisionally approved. Your study can only commence once ethics approval is obtained. Please forward a copy of your ethics clearance certificate as soon as the study is approved by the ethics committee for the CEO's office to give you the final approval to conduct the study.

Supported / ~~not supported~~

Dr. M.I. Mofokeng
Clinical Director
DATE: 12/6/2015

Approved/not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 17/6/2015

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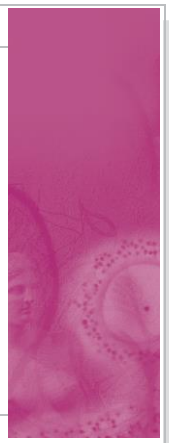
Articles are presented in numerical order 1-7

RESEARCH ARTICLE

Implications of performing laparoscopic-assisted vaginal hysterectomy versus abdominal hysterectomy on suitable patients in a South African hospital setting



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Objectives. To compare short-term clinical results with standard abdominal hysterectomy (AH), to investigate the feasibility of registrar training in laparoscopic-assisted vaginal hysterectomy (LAVH), and to investigate the impact of laparoscopy in changing the route of hysterectomy in women assessed as being unsuitable for vaginal hysterectomy (VH) on clinical examination.

Methods. 104 women scheduled for AH for benign uterine conditions were enrolled in the study. Criteria for inclusion were uterine size ≤14-week pregnancy, width ≤9 cm and length ≤14 cm. Clinical ovarian pathology and uterine prolapse were criteria for exclusion. Patients were divided into two groups matched with respect to age, parity, previous pelvic surgery and indications for hysterectomy. Laparoscopic assessment of the pelvic organs before VH was performed in 58 of the 104 patients in the study, and 46 patients had AHs without laparoscopic assessment.

Results. VH facilitated by laparoscopic assessment was successful in all cases, with no need to convert to the abdominal route. The time required for LAVH compared with AH was longer, but not significantly so (mean 59.3 minutes v. 57.2 minutes). Blood loss was found to be less with LAVH than with AH, and postoperative pain and need for analgesia were significantly less ($p<0.001$). Postoperative hospital stay was significantly shorter in the LAVH group (2.4 days) than in the AH group (3.9 days) ($p<0.001$).

Conclusions. There was shorter hospital stay, less need for analgesia, less intraoperative bleeding and better patient satisfaction with LAVH. Moreover, LAVH decreased the number of hysterectomies done abdominally.

Since the first case report of laparoscopic hysterectomy (LH) by Reich *et al.*,[1] this minimally invasive technique is being increasingly utilised. The advantages of LH are similar to those of vaginal hysterectomy (VH), including minimal postoperative discomfort and less need for analgesics, a shorter stay in hospital and quicker return to normal daily activities. There are also fewer postoperative complications, and hospital costs are reduced.[2-4]

Hysterectomy is one of the most commonly performed operations in developed countries. It is estimated that approximately 20% of women living in England and Wales will have undergone a hysterectomy before the age of 55.[5] Most surgeons perform up to 80% of procedures by the abdominal route.[6] This can in part be explained by personal preference, but is mainly due to lack of training and experience leading to reluctance to perform VH in nulliparous women in the presence of uterine enlargement or in women with previous pelvic surgery or previous caesarean section. The above factors should not be considered contraindications to VH, and there are publications that support this view.[7,8] The rationale for LH is to convert an abdominal hysterectomy (AH) into a laparoscopic/vaginal procedure and thereby reduce trauma and morbidity. In the USA before the introduction of LH, only 23% of women under the age of 60 underwent VH. The introduction of LH increased the proportion of VHs to 33%.[9]

In South Africa there is a lack of nationwide statistics. The year before the initiation of this study, VHs comprised only 9.8% of all hysterectomies at Johannesburg Hospital (Fig. 1). This situation was attributed to inadequate training, patient ethnic group, previous surgery, nulliparity and absence of uterine prolapse. Ethnicity may explain the relatively low rate of VH in our country. In an epidemiological study performed in the USA the authors found that 75% of hysterectomies performed in

African-Americans were for uterine fibroids, which are a contraindication to VH. Inadequate training may have produced a generation of gynaecologists who are not happy to perform VH in the absence of prolapse in spite of the well-documented advantages of VH in comparison with AH.

Patients and methods

This comparative study investigated LAVH (study group) against AH (control group). It was approved by the Ethics Committee of the University of the Witwatersrand.

Study group

The study group comprised women admitted for AH for benign uterine conditions who were selected to undergo LAVH, provided they met the following criteria:

- Uterine size not exceeding a 14 weeks pregnant uterus on clinical examination.
- Uterine size not to exceed 14 cm length and 9 cm width on ultrasound examination.
- No evidence of ovarian enlargement or any indication for oophorectomy.
- Nulliparous women without uterine prolapse, women with previous pelvic surgery and women with previous caesarean section were included in the study group.

Any patient who was considered to be suitable for VH on routine standard clinical assessment by a consultant was excluded. All patients booked into the author's unit for AH were entered into the study group provided they met the inclusion criteria described above. The laparoscopic assessment was carried out by the author in all cases, and all the VHs were performed by registrars in training under the supervision and with the assistance of the author.

Control group

Controls were selected from gynaecological units not participating in the study. They were matched with respect to age, parity, previous pelvic surgery and indications. All the AHs were carried out by the registrars in training at Johannesburg Hospital under the supervision and with the assistance of the consultants. Unfortunately it was not practically possible for the same surgeon to operate on all the control patients. However, this limitation was noted when comparing the outcomes in the two groups.

LAVH

Before proceeding to VH a laparoscopic assessment of the pelvis and pelvic organs was performed. The laparoscopic component of VH includes assessment of the pelvic organs, release of adhesions and treatment of endometriosis where necessary (up to stage I of LAVH). Provided the entry conditions were confirmed and any adhesions could be released laparoscopically, VH was performed. The laparoscope was left in position to assess the progress and any complications of the procedure. Following VH and the closure of the peritoneum and vaginal vault, laparoscopy was performed in all cases to assess haemostasis and flush out blood and debris.

All patients received prophylactic antibiotics during surgery.

Data analysis

Comparative parameters were tested for significant differences using Student's *t*-test for normally distributed continuous data and the Mann-Whitney test for non-parametric data. A *p*-value of <0.5 was considered to be statistically significant.

Outcome measures

VHs facilitated by prior laparoscopic assessment and AHs were compared as follows:

1. Operative parameters and complications

- Operation time (minutes).
- Specimen weight, to demonstrate any difference in uterine size between groups.
- Blood loss intraoperatively (estimated) and need for intraoperative blood transfusion. Blood loss was assessed by best estimated volume loss.
- Necessity of converting the VH to an abdominal approach.
- Operative complications.

2. Short-term clinical outcome

- Hospital stay (days).
- Postoperative need for blood transfusion. If blood transfusion was required, the volume of blood given was recorded.
- Postoperative pain – the pain scale is a simple 10 cm visual analogue scale, which has been used previously and is easily comprehended by patients.
- Amount, frequency and type of analgesia required.
- Febrile morbidity and the need for antibiotics.

The laparoscopic part of the study did not require additional funding. The gynaecological theatre was equipped with the necessary laparoscopic instruments to perform laparoscopic surgery.

Results

There were 58 cases in the study group (LAVH) and 46 in the control group (AH). All VHs facilitated by laparoscopic assessment were successful, with no need to convert to the abdominal route. Patient characteristics at inclusion, the indications for hysterectomy and the weights of the uteri were similar in the two groups of patients (Tables I and II). No cases from the study group were excluded. Seven patients in the LAVH group required adhesiolysis and 2 were found to have minimal

Table I. Characteristics of the study and control groups (means (ranges))

	LAVH (*N*=58)	AH (*N*=46)
Age (yrs)	44.3 (28 - 56)	42.7 (28 - 60)
Weight of uterus (g)	151.4 (86 - 286)	135.2 (65 - 280)
Parity	2.4 (0 - 5)	2.6 (0 - 5)

Table II. Indications for hysterectomy in the study and control groups (patients could have more than one indication)

	LAVH (*N*=58)	AH (*N*=46)
Multifibroid uterus	36	30
Chronic pelvic pain	31	23
Menorrhagia	27	22
Polyp protruding through cervix	4	1
Cervical intra-epithelial neoplasia III	4	8
Severe dysmenorrhoea	7	3
Deep dyspareunia	5	2
Endometrial hyperplasia	0	1
Mentally retarded	0	1

endometriosis necessitating ablation. No gross ovarian abnormality was found.

The time required for surgery was not significantly longer for LAVH than for AH (59.3 minutes v. 57.2 minutes). Postoperative hospital stay and convalescence were significantly shorter in the LAVH group, with a hospital stays of 2.4 days for LAVH and 3.9 days for AH. There was significantly less postoperative pain and less need for analgesia in the LAVH group. Blood loss during the procedure was significantly less in the LAVH group than in the AH group (Table III), although no patient received a blood transfusion. One major complication occurred in the AH group and none in LAVH group (Table IV). This was deep-vein thrombosis presenting with pyrexia and resolving with antibiotics and enoxaparin. A temperature above 38ºC more than 24 hours after the operation and necessitating intravenous administration of antibiotics was recorded in 7 patients in the AH group but none in the study group. Of women who underwent LAVH, 74% (43 of 58) had at least one of the five conditions (a large uterus, nulliparity, previous caesarean section, previous laparotomy and fibroids protruding through the cervix) that are generally considered relative contraindications to VH.

The number of VHs performed at Johannesburg Hospital since 1995 and the impact of the study on VH numbers is shown in Fig. 1. The proportion of VHs increased from 9.8% of all hysterectomies at the beginning of the study period (July 2001) to 19.2% at completion of the study (December 2004).

Discussion

This study demonstrated that all patients admitted for AH who met the inclusion criteria set up for the study could be operated on vaginally after being assessed laparoscopically. The benefit of laparoscopic assessment is that, where necessary, adhesions can be released, the ovary visualised and endometriosis treated. Although LAVH necessitated slightly longer theatre time than AH, this was more than compensated for by the well-documented postoperative benefits of shorter recovery time and hospital stay and less pain.[2-4]

Hysterectomy is the most common gynaecological operation, and the vaginal route is preferable. However,

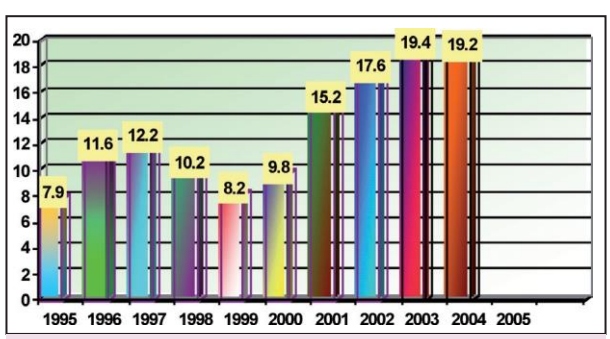

Fig. 1. Vaginal hysterectomies performed at Johannesburg General Hospital (as a percentage of all hysterectomies), 1995 - 2004. The study period was July 2001 - December 2004.

Table III. Operation time and postoperative course in the study and control groups (mean (range))

	LAVH *N*=58	AH *N*=46	*p*-value
Operation time (min)	59.3 (40 - 90)	57.2 (40 - 90)	0.60*
Hospital stay (days)	2.4 (2 - 5)	3.9 (3 - 5)	<0.001*
Median postoperative pain as assessed by VAS	Day 1: 3 (2 - 5)	6 (4 - 7)	<0.001†
	Day 2: 1 (0 - 3)	4 (2 - 5)	<0.001†
Number of opiate injections required	2.4 (2 - 4)	4.2 (3 - 5)	<0.001*
Estimated blood loss (ml)	152 (50 - 300)	254 (75 - 750)	<0.001†

*Student's *t*-test.
†Mann-Whitney test.
VAS = visual analogue scale.

Table IV.	Complications in the immediate postoperative period in the study and control groups		
		LAVH (*N*=58)	AH (*N*=46)
Major	Haemorrhage necessitating blood transfusion	0	0
	Urinary tract damage	0	0
	Pulmonary embolism	0	0
	Bowel damage	0	0
	Deep-vein thrombosis	0	1
Minor	Pyrexia requiring antibiotics	0	7
	Wound sepsis	0	0
	Wound erythema	1	0

the vaginal procedure seems to be ignored by most surgeons, resulting in an extremely high rate of AH.[6] The main indication for LH is to convert AH into a vaginal operation, or a difficult VH into an easy one.

The presence of adhesions and endometriosis, locations of fibroids and the feasibility of VH in the absence of uterine prolapse can in my view best be assessed by laparoscopy. The results of this study are in agreement with those of Kovac *et al.*,[10] who demonstrated that laparoscopy before AH made it possible for 91.3% of women to undergo an uncomplicated VH. In our study all cases in which AH was planned went on to VH and in no case was it necessary to convert from VH to AH.

Our results are not in agreement with some studies, which showed that LH significantly increase theatre time,[11,12] as it is not so much the laparoscopy itself that increases the operating time but the amount of hysterectomy performed laparoscopically as opposed to vaginally. Laparoscopic surgery should be converted to a vaginal procedure as early as possible (e.g. after adhesiolysis, assessment of the ovaries and location of fibroids, as in our study). Nothing is gained by continuing dissection, since this not only considerably and unnecessarily prolongs the surgery but also increases the risk of visceral damage and haemorrhage. In agreement with the above studies, we found length of hospital stay to be significantly shorter and the need of analgesia to be significantly less for LAVH than for AH. Postoperative pain as assessed by the VAS was less after LAVH than after AH, explaining the lesser need for analgesia in LAVH group.

There is no specific cut-off age for removal of the ovaries in our institution. In this study removal of the ovaries was common among women over 45 having an AH and almost universal among those over 47. In the LAVH group we managed to remove the ovaries vaginally in only 3 out of 10 women over the age of 45. This may be considered as a limitation of this study. The 7 women whose ovaries we failed to remove were not at high risk for ovarian malignancy, and laparoscopic assessment showed their ovaries to be macroscopically normal. Removal of the ovaries in order to prevent ovarian cancer remains controversial for women not at high risk. It is estimated that about 200 oophorectomies will be needed to avoid 1 case of ovarian cancer.[13]

The results of this case control study, with relatively small numbers of patients who were not randomised, demonstrated that LAVH can be performed safely on selected patients who would otherwise be scheduled for AH. The finding of less operative bleeding in the LAVH group is in agreement with another study.[14] We did not perform routine postoperative measurement of the haemoglobin (Hb) concentration to document the above statement, but none of the patients received a blood transfusion. However, the fact that we did not routinely measure the postoperative Hb may be considered a weakness of the study, as objective proof of different amounts of blood loss could not be documented.

Although cost analysis and patient satisfaction are out of the scope of this study, shorter hospital stay is likely to save costs. Patients who had had LAVH reported returning to their normal daily activities sooner and having a better quality of life than patients who had had AH.

There were no major complications in the two groups, other than one deep-vein thrombosis in a woman who underwent AH. Seven patients had pyrexia at 24 hours after AH necessitating antibiotic treatment, which is regarded as a minor complication. The fact that we found no case of pyrexia in the postoperative period in the LAVH group is in agreement with another study[15] that found less postoperative febrile morbidity after VH compared with AH.

There are reports that uteri up to a 14-week size can be removed vaginally, with the proviso that it may be necessary to convert to AH,[16] or at least that a VH can be attempted while the patient is under anaesthetic.[17] In my view this may lead to unacceptable complications such as haemorrhage necessitating blood transfusion, pose a risk of bladder and bowel damage, increase theatre time and mean disappointment for the patient. If there is doubt about the likelihood of successful VH it may be wiser to proceed directly to AH. A skilful vaginal surgeon can remove large uteri; one surgeon has reported removing uteri of 1 kg and larger.[18] Such cases are not appropriate for the training of registrars in vaginal surgery or VH. Also, we should not abandon the laparoscope and schedule the next woman with a 14-week uterus for a VH if there is any doubt that this procedure will be successful. LAVH may offer a transition into more aggressive vaginal surgery.

In this study laparoscopic assessment after performing VH may have improved haemostasis, with flushing out

of clots and blood preventing vault haematoma and febrile morbidity in the immediate postoperative period. According to Marshall and Smith,[19] the amount of blood clots that remain in the pelvis after VH which has seemed to be dry and haemostatic is surprising. Flushing out the clots may have been beneficial for the patients in our study.

One of the limitations of the study was that the same surgeon was not able to do all the control procedures. The outcome of the study was influenced by the experience of the registrars in both groups and also by the experience of the consultants in the control group. A major difficulty, not only for this study but for any randomised trial in surgery, is the uncontrollable effect the surgeon has on the outcome.

The American College of Obstetricians and Gynecologists[20] guidelines recommend that choice of the route of hysterectomy should depend on the patient's anatomy and the surgeon's experience. If the gynaecologist did not perform enough VHs during training, he or she may be inclined to perform hysterectomy by the abdominal route when it could safely be performed vaginally. Fear of litigation should complications arise is another factor affecting choice of procedure.

In 1998 the Royal College of Obstetricians and Gynaecologists[21] recognised that the route of hysterectomy should be audited to determine the optimal rate of VH. The audit should include surgeon preference, degree of descent of the uterus and need and opportunity for more training in vaginal surgery. In South Africa there is a lack of national statistics, but at Johannesburg Hospital the rate of VH was 9.8% a year before the beginning of the study and reached 19.2% by the end (Fig. 1), which is significant if one takes into consideration that the vast majority of our patients are black Africans with benign conditions such as uterine fibroids.

The fact that all the VHs in this study were done by registrars under the author's supervision and with his assistance highlights the important issue of training and teaching. There is a need nationally for more training in VH as well as other vaginal procedures to produce a new generation of vaginal surgeons capable of performing VHs in the absence of uterine prolapse for selected benign conditions, as there are too few opportunities to encounter uterovaginal prolapse to allow adequate training in vaginal surgery. This study provides evidence of the feasibility of registrar training in VH using laparoscopic assistance.

Registrars in teaching hospitals must receive more training in VH. The present number of VHs that a registrar is required to perform before he or she can attempt the College of Medicine examinations is not sufficient to ensure competency in this procedure in specialist practice. All possible efforts must therefore be employed for registrars to get more exposure and training in VH.

Conclusion

Challenging the routine contraindications to VH by the use of laparoscopic assessment can lead to an increased number of VHs. Deficient registrar training in VH is a major problem in our postgraduate programme, and this study provides evidence of an additional opportunity to allow registrars to safely perform more VHs.

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Review article

Evidence-based guidelines for vaginal hysterectomy of the International Society for Gynecologic Endoscopy (ISGE)

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ABSTRACT

Objective: This project was established by the International Society for Gynecologic Endoscopy (ISGE) to provide evidence-based recommendations on the selection of women in whom vaginal hysterectomy can be safely performed.

Study design: The ISGE Task Force for vaginal hysterectomy for non-prolapsed uterus defined key clinical questions that led the literature search and formulation of recommendations. The search included Medline/PubMed and Cochrane Database. English language articles were reviewed from January 2003 to January 2018, in conjunction with reviews published by the American College of Obstetricians and Gynecologists (ACOG) and the American Association of Gynecologic Laparoscopists (AAGL). The bibliographies of selected works were also checked to acquire additional data where relevant. The available information was graded by the level of evidence using the approach developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group. For each clinical question, the ISGE recommendations were defined in accordance with the evidence quality.

Results: Six recommendations on patient selection for vaginal hysterectomy, including two grade 1B and four grade 2B recommendations were established.

Conclusion: Vaginal hysterectomy for non-prolapsed uterus is the treatment of choice for many gynaecological patients in whom hysterectomy is indicated. It may be safely executed, and thus, should be offered to a large group of appropriately selected women, who today are operated in the main by the abdominal or laparoscopic approach. All efforts should be directed towards teaching the technique of vaginal hysterectomy during residency.

Contents

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Introduction

Hysterectomy is one of the most common operative procedures for benign uterine diseases [1]. It can be performed abdominally, vaginally, or laparoscopically, with or without robotic assistance. The advantages provided by vaginal hysterectomy (VH), laparoscopic-assisted vaginal hysterectomy (LAVH), and laparoscopic hysterectomy (LH) over abdominal hysterectomy (AH) include less postoperative pain, less need of analgesia, shorter hospital stay, and more rapid recovery and return to daily activities [2–6]. Additionally, there are fewer intra-operative and postoperative complications reported with vaginal hysterectomy as compared with abdominal hysterectomy (AH) or laparoscopic hysterectomy (LH) [7–9]. AH for benign uterine conditions remains the chosen route worldwide. This preference is largely due to a lack of experience in VH, resulting in the surgeon's reluctance to perform VH, especially in patients without uterine prolapse, with uterine fibroids, previous caesarean sections, previous laparotomies, as well as in nulliparous women. Correctly challenging these contraindications may lay the foundation for implementing different approaches towards an increased number of VHs [10–13]. Globally, the rate of LH has been shown to be increasing, without a significant reduction in AHs. Seventy to 80% of hysterectomies have been shown to be carried out via the abdominal approach, according to all large-scale surveys, except when treating uterovaginal prolapse, for which the vaginal route is generally preferred. This latter indication accounts for about 10% of all hysterectomies conducted worldwide [14]. This increase in LH has thus been incurred at the expense of VH while, ideally, it is the VH rate that should increase at the expense of the AH rate. This decrease in the rate of VH is demonstrated clearly in Australia, where the rates of VH have dropped between 2001 and 2015 by 53% in younger patients and 29% in the older age group [15]. Nigeria demonstrated a further decrease in VH, where the vaginal route was utilised in approximately 12% of hysterectomies performed in a teaching university hospital. In Norway, the preferred route of hysterectomy has changed in favour of LH, where the number of VHs have decreased to below 10%, mainly performed for utero-vaginal prolapse [16]. It is a common perception that the decreasing VH rate, which came about as a consequence of the dependence on LH, may be at least partially attributed to the impact of the industry that manufactures and promotes the laparoscopic equipment.

A lack of adequate training offered in VH is also of relevance in new generations of gynaecologists performing total laparoscopic hysterectomy (TLH) in patients who may have otherwise undergone an uncomplicated VH. In a study performed in the USA in 2011, by Antosh *et al.,* only 41.7% of residents reported VH as their preferred route of hysterectomy, as compared to 47.1% who preferred laparoscopic approaches [17]. Lee and King, considering the difficulties in teaching both LH and VH during residency, have suggested that TLH represent the new gold standard in minimally invasive approaches for hysterectomy, while the professional societies, such as the American College of Obstetricians and Gynaecologists (ACOG) and the American Association of Gynecologic Laparoscopists (AAGL), have been encouraged to direct more resources to promote education in and practice of LH if a substantial decrease in AH is truly our primary goal (http://www.contemporaryobgyn.net/modern-medicine-feature-articles/vaginal-versus-laparoscopic-hysterectomy). However, this highlights a fundamental problem currently facing clinical gynaecology, namely insufficient VH training/practice due to the inadequate experience of junior trainers in VH, and the consequent lack of appreciation of the benefits afforded by VH.

VH for the non-prolapsed uterus is an appropriate alternative for a large group of women who are predominantly operated upon via LH or AH today. The International Society for Gynaecologic Endoscopy (ISGE) was motivated to carry out this endeavour to establish evidence-based recommendations on the selection of women for VH.

Materials and methods

The ISGE Task Force for vaginal hysterectomy for the non-prolapsed uterus defined key clinical questions (Panel 1), which led to the literature search from Medline/PubMed and the Cochrane Database. English language articles, both original works and previous reviews (published from January 2003 to January 2018, with the bibliographies of selected works checked to identify additional references and relevant data), were analysed in conjunction with reviews/guidelines published by the ACOG and AAGL. The available information was graded by the level of evidence, using the GRADE approach, proposed and developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group (http://www.gradeworkinggroup.org) (Table 1). In accordance with the evidence quality, the recommendations were established for each clinical question. No Ethical Committee approval was required for this work.

Literature review and recommendations

Most hysterectomies are performed for benign indications such as symptomatic uterine fibroids, abnormal uterine bleeding, endometriosis, and prolapse. The hysterectomy rates differ considerably among countries [18]. Almost 30% of women in the USA are submitted to the procedure by the age of 60 years, while the hysterectomy rates in developing countries are lower (https://www.medscape.com/viewarticle/712569). In the USA, almost 600.000 hysterectomies are performed yearly for benign disease. In 2007, Wu *et al.* reported on hysterectomy rates in the USA for the year 2003, and found that the abdominal route was the most common (66.1%), followed by vaginal (21.8%) and laparoscopic (11.8%) routes [19].

Question 1: Which route of hysterectomy should be considered as the first choice in women undergoing hysterectomy for benign indications?

Question 2: Should nulliparity, absence of utero-vaginal prolapse, uterine fibroid/(s), previous caesarean section, premalignant cervical and/or premalignant endometrial disease be considered as contraindications to vaginal hysterectomy?

Question 3: Which factors should be considered prerequisites for a successful vaginal hysterectomy?

Question 4: In women without adnexal disease and who are not at an increased risk for cancer, should routine removal of the ovaries and fallopian tubes be recommended during vaginal hysterectomy?

Panel 1. Vaginal hysterectomy – key clinical questions.

Table 1
Grading of recommendations and quality of supporting evidence.

Grade of recommendation	Risk/benefit	Quality of supporting evidence
1A. Strong recommendation, high quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
1B. Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
1C. Strong recommendation, low quality evidence	Benefits appear to outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.
2A. Weak recommendation, high quality evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
2B. Weak recommendation, moderate quality evidence	Benefits closely balanced with risks and burdens, some uncertainly in the estimates of benefits, risks and burdens.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
2C. Weak recommendation, low quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.

The introduction of robotics has changed the rates in favour of robotic hysterectomy (RH) with a further decline not only in VH but also in conventional LH [15,20]. Recent findings in the USA hospitals, where robotics have been introduced, have indicated that the use of abdominal hysterectomy has declined from 66,1% in 2003 to 54,2% by 2010. The use of VH declined throughout, from 24.8% in 1998 to 16,7% in 2010. Use of LH increased to a peak of 15.5% of cases in 2006, and then declined to 8.6% of procedures in 2010, whereas use of RH increased from 0,9% in 2008 to 8,2% in 2010 [20]. Robotics do not truly make a difference in increasing the ratio of VH and conventional LH in favour of AH, as evidenced by the fact that the latter remained at a constant 64% nationwide in the USA in 2009 [21].

Comparison of different approaches to hysterectomy

Currently available evidence indicates that minimally invasive procedures, including VH and LAVH/LH/RH, should be the preferred route of hysterectomy, as they offer the same benefits, and avoid large and painful abdominal incisions that are needed for AH. Additionally, longer hospital stay and a delay in returning to daily activities are also avoided [2,5,22,23]. Specifically, the 2009 Cochrane review found that VH, as compared to AH, is associated with a shorter hospital stay, the ability of the patient to resume normal daily activities more quickly, and fewer infections and episodes of raised temperature after surgery [2]. LH, as compared to AH, has the same advantages as VH. While there was less blood loss and fewer wound infections in LH, as compared to AH, LH took longer and was associated with a greater risk of damaging the ureter or the bladder [2]. No differences were found between LH and VH with regards to their benefits. However, when compared to VH, LH takes 39.3 min longer than VH, on average, and is associated with a higher rate of complications [2]. Fewer complications have been associated with VH, when comparing this method of hysterectomy to all other routes. In 2015, a further Cochrane review by Aarts et al. confirmed the findings of Nieboer et al. regarding the advantages of VH over the other routes of hysterectomy, including RH [2,22]. He found that RH presented no difference in outcomes when compared to conventional LH, beneficial or otherwise. Thus, both Cochrane reviews concluded that VH should be considered the first choice for hysterectomy in the treatment of benign conditions (Grade: 1B).

The 2009 ACOG guidelines on choosing the route of hysterectomy for benign disease state that, when feasible, VH is the safest and most cost-effective route by which to remove the uterus [23]. LH is an alternative to AH for those women in whom a VH is not indicated or possible [23]. The AAGL adopted the statement advising that surgeons without requisite training and skills required for the safe performance of VH or LH should enlist the aid of colleagues who do, or should refer patients requiring hysterectomy to such individuals for their surgical care [24].

In June 2017, the ACOG confirmed their 2009 statement defending VH as the route of choice wherever feasible. This statement was based upon data collected over the course of almost a decade, which indicated that VH was associated with better postoperative outcomes when compared with other approaches to hysterectomy (https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co701.pdf?dmc=1&ts=20170702T0930167819). It was concluded that LH serves as a preferable alternative to open AH for patients in whom VH is contraindicated or not feasible (Grade2B). Through their analysis of the data captured, the ACOG found that the introduction of RH lead to a decrease in both LH and a VH. VH in particular had decreased from 25% in 1998 to 17% in 2010.

The evidence-based formal guidelines for the preferred route of hysterectomy have been largely neglected by surgeons, and as such, the choice for hysterectomy is usually based on subjective preferences rather than standardised selection criteria for the

route of hysterectomy. When formal guidelines were used to determine the route of hysterectomy, VH was performed in 90% of the patients treated, and in 100% of the patients in whom the pathology was confined to the uterus [25]. In comparison, when formal guidelines were not incorporated in the decision-making process, VH was reported in 42% of the patients treated, and in 64% of the patients in whom the pathology was confined to the uterus. Should guidelines be used to assist clinical decision-making, potential savings of $1.2 million (USA) could be attained for every 1000 hysterectomies performed vaginally, as well as a reduction of 20% in complications associated with the procedure [25]. A cost effectiveness analysis undertaken with the eVALuate study revealed that the vaginal approach was more cost-effective compared to the laparoscopic route, primarily due to the use of disposable instruments in laparoscopy [3]. Sculpher et al. found that LH cost an average of $780 (USA) more than VH, per patient. With more than 500.000 hysterectomies performed annually in the United States, and more than 100.000 in the United Kingdom, the vaginal approach seems even more relevant in this time of economic strain [26].

To sum up, it is evident from the literature that the vaginal route should be considered the preferred choice. VH skill should not be sacrificed in favour of LH. Academic institutions worldwide are urged to review a strategy in order to retain the skill of VH, via appropriate training programs.

Factors influencing the route of hysterectomy

Surgeon training and experience have often been deemed particularly influential leading factors for the selection of the most appropriate approach to hysterectomy. The lack of training in VH has been raised by several authors as being an important factor, with lack of experience in vaginal surgery leading to gynaecologists having a dependence on the abdominal and/or laparoscopic routes when contemplating hysterectomy [27–29]. Training in vaginal surgery during residency is important in order to challenge supposed contraindications to VH. It has been shown that VH can be safely performed in women without uterine prolapse, in those with an enlarged fibroid uterus up to 12 weeks gestation, in patients with a history of one or more previous caesarean sections, previous laparotomies, premalignant cervical or endometrial pathology, as well as in nulliparous women. Correctly challenging these contraindications may lead to an increased number of VHs [10–13] (Grade: 2B).

Aside from personal training, factors that are considered prerequisites for a successful VH are vaginal accessibility, together with the size and mobility of the uterus. The confirmation of pathology confined or not confined to the uterus also influences the route of hysterectomy selected [25]. The use of a set of guidelines on the route of hysterectomy – incorporating vaginal accessibility, uterine size and mobility, and pathology confined to the uterus – has been proposed [25]. In a randomised trial where residents followed these guidelines for selection of hysterectomy, the percentage of VHs performed for benign conditions was found to be more than 90% (https://www.omicsonline.org/open-access/28-years-of-using-hysterectomy-guidelines-to-determine-the-feasibility-of-vaginal-hysterecto- my-2161-0932-1000375.php?aid=72317). When pathology is not confined to the uterus (adnexal pathology, known or suspected, adhesions, and endometriosis), thereby precluding VH, it is advisable to perform LAVH to restore anatomy or to free the adnexal before proceeding to VH [5] (Grade: 2B). LAVH has its place where there is uncertainty of a successful VH, or in order to perform adhesiolysis, treat endometriosis, and restore pelvic anatomy. LAVH is especially needed when prophylactic oophorectomy is required, as it is not always possible for the ovaries to be removed vaginally. In a study by Chrysostomou, it was demonstrated that by performing laparoscopies in patients who were considered unsuitable for VH, all the subjects were able to proceed to an uncomplicated VH (www.sajog.org.za/index.php/SAJOG/article/download/18/93). The author reached the conclusion that the laparoscopic approach should be converted to a vaginal procedure as soon as possible (e.g. after adhesiolysis, treatment of endometriosis, adnexectomy, location of the fibroids). Nothing is gained by continuing laparoscopic dissection, as this unnecessarily prolongs the surgery and increases the risk of visceral damage. As the surgeon's confidence increases, ultimately more cases will be achieved by VH alone, and the overall operative risks may thus be decreased.

Vaginal accessibility

Vaginal accessibility is determined by assessing 3 key components: the angle of the pubic arch, the shape of the vagina, and the uterine descent. A pubic arch that is wide, or more than 90 ^{0}, allows for easier access to the uterus and placement of instruments, facilitating the vaginal approach. However, with a small 1–2 cm posterior midline episiotomy, vaginal accessibility may be obtained even when the pubic arch is less than 90 ^{0} [13,23,30].

The shape of the vagina, especially the breadth of the vaginal apex, is best assessed during vaginal examination. A vaginal apex of 3 cm wide facilitates a vaginal approach, as it provides ample space for anterior and posterior entry, and improves lateral visualization of the vasculature [13,30].

The ACOG has stated that VH is indicated for patients with a mobile uterus of less than 12 weeks gestational size (Grade: 1B) [23]. It is a common belief that uteri up to 12 weeks gestation can be delivered vaginally without any additional reduction procedures.

Pathology not confined to the uterus

When pathology is not confined to the uterus, and if the surgeon is uncertain of successful vaginal removal of the uterus, then it is advisable to perform laparoscopy to restore anatomy before undertaking VH. The decision to perform elective salpingoophorectomy is not dependent on the route of hysterectomy, and is not a contraindication to the performance of VH [31]. This removal of the ovaries and Fallopian tubes during VH is recommended in women who are at high risk of developing ovarian cancer. Mandatory salpingectomy is recommended in those who are carriers of the germ line mutation BRCA1 and BRCA2 genes, in which the occurrence of serous tubal intraepithelial carcinoma (STIC) has been established (Grade: 2B) [31]. However, removing the fallopian tubes and ovaries in women with non-proven genetic or familial risk of ovarian cancer cannot be justified in 40–80% of case [31]. It is important to consider that prophylactic salpingo-oophorectomy in premenopausal women at low risk for ovarian cancer is associated with a higher risk of developing osteoporosis and cardiovascular disease, and has thus been linked to reduced survival rates [32–35]. Bearing this in mind, in the absence of ovarian disease and personal/family history of breast/ovarian carcinoma, routine removal of the ovaries during VH for benign uterine disease is not recommended, as the risks outweigh the benefits (Grade: 2B). The performance of prophylactic bilateral salpingectomy with ovarian conservation during vaginal hysterectomy, as suggested by the ACOG in 2015 (https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co620.pdf?dmc=1), has been found to prevent a diagnosis of ovarian cancer in 1 of every 225 patients undergoing surgery. Furthermore, the implementation of salpingectomy helps prevent death from ovarian cancer in 1 in every 450 women having surgery [36]. Prophylactic bilateral salpingectomy with ovarian

conservation during VH should therefore be undertaken routinely (Grade 2B) [36].

The success of removing ovaries and Fallopian tubes vaginally varies greatly, and is reported to range between 77% and 915% [36–39]. Once VH is performed, a moistened pack is gently placed in the pelvis to prevent bowel from obscuring visualization. The transected tube and utero-ovarian ligament are pulled medially into the field until the round ligament is visualised. The round ligament is then clamped, cut and ligated. This allows further descent of the tubo-ovarian pedicle into the field, which can be clamped just above the superior tip of the ovary and then ligated [40]. If there is initial uncertainty surrounding the success in removing the ovaries vaginally, laparoscopic-assisted vaginal hysterectomy (LAVH) should be employed first. Similarly, if a problem arises in removing the ovaries and the tubes during a VH, then laparoscopic assistance should be used to complete the surgery (Grade: 2B). In certain circumstance, such laparoscopic skills may not be easily obtained.

An algorithm for women undergoing hysterectomy for benign indications is shown in Fig. 1. A summary of ISGE recommendations for VH are presented below, in Panel 2 .

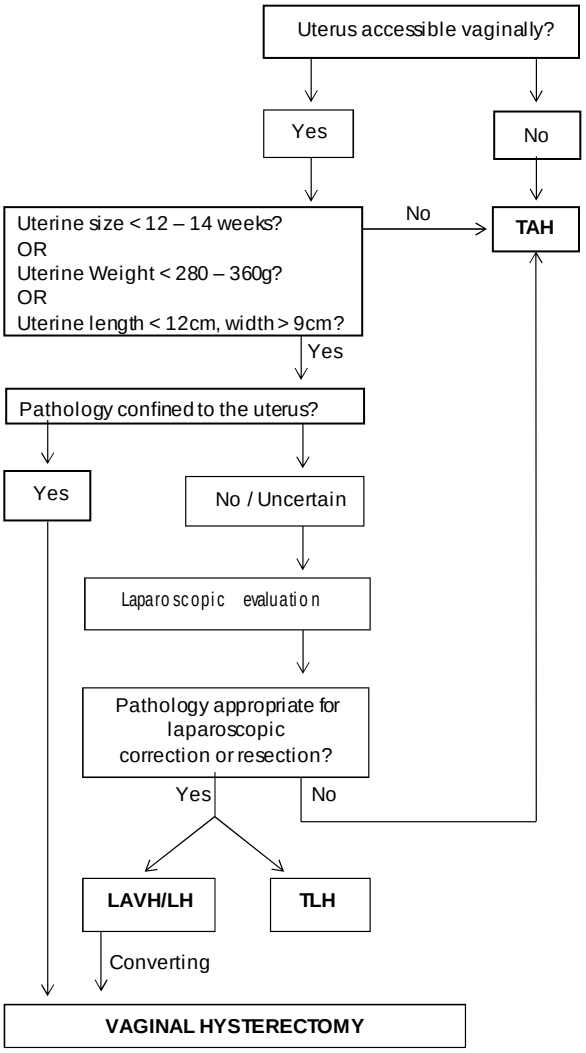

Fig. 1. Determining the route of hysterectomy for benign disease (clinical examination and pelvic ultrasonography-based approach). *Abbreviations:* LAVH, laparoscopic-assisted vaginal hysterectomy; LH, laparoscopic hysterectomy; TAH, total abdominal hysterectomy; TLH, total laparoscopic hysterectomy.

ISGE Recommendation 1: The vaginal hysterectomy should be considered as the first choice for benign indications (**Grade 1B**).

ISGE Recommendation 2: The laparoscopic approach should be considered when vaginal hysterectomy is contraindicated or not technically possible (**Grade 2B**).

ISGE Recommendation 3: Nulliparity, absence of utero-vaginal prolapse, uterine fibroid, previous caesarean sections, as well as premalignant cervical and endometrial disease should not be considered as contraindications to vaginal hysterectomy (**Grade 2B**).

ISGE Recommendation 4: The surgeons should pay attention to the clinical factors which facilitate vaginal hysterectomy and optimise patient outcome (**Grade 2B**).

ISGE Recommendation 5: Hysterectomy for benign causes is best performed vaginally if the uterus is less than 12 weeks of gestation or ≤ 280 g (preoperative clinical and ultrasound estimation, respectively), if accessible vaginally and the pathology is confined to the uterus (**Grade 1B**).

ISGE Recommendation 6: In the absence of ovarian disease and personal/family history of breast/ovarian carcinoma, routine removal of the ovaries during vaginal hysterectomy for benign uterine diseases is not recommended as the benefits outweigh the risks (**Grade 2B**); while in women at increased risk of ovarian, breast and bowel cancer, genetic counselling and routine salpingo-oophorectomy during vaginal hysterectomy should be undertaken. LAVH should also be employed in these circumstances (**Grade 2B**).

Panel 2. ISGE recommendations for vaginal hysterectomy.

Reflection

Minimally invasive approaches to hysterectomy are preferable options, based on their well-documented advantages over AH. When VH, the first line approach, is not indicated or feasible, the surgeon should choose between LH or open AH. LH is a preferable alternative in these settings. The 2015 Cochrane review concluded that RH demonstrates no significant advantage over conventional LH [7]. However, in cases where the uterine pathology precludes minimally invasive approaches, the importance of AH becomes apparent. AH also serves as an important alternative if LH or VH fail intra-operatively. Thus, while these guidelines strongly motivate for the increase in VH training, it does not aim to dismiss the importance of LH and AH, where their use is appropriate.

The clinician should assess cases by a focussed history, physical examination, and pelvic ultrasound with transvaginal probe before deciding which route of hysterectomy will most safely facilitate removal of the uterus and optimize patient outcomes, taking into account also the clinical situation (Fig. 1), and surgeon training and experience. As the most highly recommended route of hysterectomy, VH should be considered a priority among procedures to be learned by residents. Trainee gynaecologists need to be helped by Program Directors to navigate between Senior Gynaecologists with different skill mix, in learning the performance of VH.

It is essential to revive the use of VH as it is safer, more economical, and has rapid recovery rates and fewer complications among all the routes of hysterectomy. It can be expected that reducing the prevalence of LAVH will prompt the surgeon to become more proficient in VH, and to recognise that laparoscopic assistance is only necessary in specific cases.

Conclusion

VH should be considered the ideal surgical approach when hysterectomy for benign uterine disease is undertaken. The guidelines proposed here provide suggestions that the majority of patients and clinicians would consider following. Their implementation can lead to a decrease of hysterectomies performed abdominally and a significant increase in hysterectomies performed vaginally, which may be achieved without an inappropriate increase in laparoscopic hysterectomy. Clinical judgement is needed for these suggestions, as physicians must evaluate the particular needs and expectations of each patient to arrive at the best management decision for each individual case.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgments

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Review article

Evidence-based practical guidelines of the International Society for Gynecologic Endoscopy (ISGE) for vaginal hysterectomy

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ABSTRACT

Objective: The study was established by the International Society for Gynecologic Endoscopy (ISGE) to provide evidence-based recommendations in the steps that should be undertaken in successfully performing a vaginal hysterectomy for a non-prolapsed uterus.

Material and methods: The ISGE Task Force for vaginal hysterectomy for the non-prolapsed uterus defined key clinical questions regarding the surgical technique, which led the Medline/PubMed and the Cochrane Database literature search. Identified pertinent articles, published in English from 1997 to 2019, were analysed. The available information was graded by the level of evidence using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group approach. The recommendations were developed through multiple cycles of literature analysis and expert discussion.

Results: Six recommendations were established:

1. A circular incision at the level of cervico-vaginal junction is recommended (grade IC).
2. The posterior peritoneum should be opened first (grade IC).
3. Clamping and cutting the uterosacral and cardinal ligaments before or after getting access into anterior peritoneum is recommended (grade IC).
4. Routine closure of the peritoneum during vaginal hysterectomy is not recommended (grade IB).
5. Vertical or horizontal closure of the vaginal vault following vaginal hysterectomy is recommended (grade IC).
6. To insert a vaginal plug following vaginal hysterectomy is not recommended (grade IB).

Conclusion: Vaginal hysterectomy for a non-prolapsed uterus should be the preferential route for removing the uterus when hysterectomy is indicated. The ISGE provides evidence-based practical guidelines on how vaginal hysterectomy for non-prolapsed uterus should be undertaken. All efforts should be directed in teaching the surgical technique of vaginal hysterectomy during residency.

Contents

Abbreviations: AH, abdominal hysterectomy; GRADE, grading of recommendations, assessment, development and evaluation; ISGE, International Society for Gynecologic Endoscopy; LH, laparoscopic hysterectomy; VH, vaginal hysterectomy.

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Introduction

Hysterectomy is one of the most common operative procedures for benign gynecological diseases [1,2]. It can be performed abdominally, vaginally or laparoscopically, with or without robotic assistance. The benefits of vaginal hysterectomy (VH) and laparoscopic hysterectomy (LH) over abdominal hysterectomy (AH) have been widely reported [3–7]. The advantages provided by VH, with or without laparoscopic assistance, include less post-operative pain, less analgesia needed, shorter hospital stay, and a more rapid recovery and return to daily activities [7–9]. Furthermore, following all the parameters of the least invasive non-scar hysterectomy, VH is associated with fewer intra-operative and post-operative complications as compared with AH or LH [10–14]. In spite of these benefits, all large-scale surveys of hysterectomy practice show that 70–80 % of hysterectomies are performed via the abdominal approach [11]. This preference is largely attributed to a lack of experience in VH, resulting in the surgeon's reluctance to perform VH, especially in patients without uterine prolapse, with uterine fibroids, previous caesarean sections, previous laparotomies, as well as in nulliparous women. The vaginal route has been found to be a safe option for these indications for hysterectomy, and may lead to an increased number of VH [15–23].

Globally, the focus on performing LH appears to result in significant reductions in rates of VH, without perceptible impact on the AH rates [14,24–30]. In Belgium, for example, the focus on LH resulted in VH rates dropping from 34 % in the early 1990s to only 8 % in 2006, and in Norway from 9 % in 2001 to only 3 % in 2005, mainly performed for utero-vaginal prolapse. In some regions (e.g. certain hospitals in India, Belgium, Norway and the US), the percentage of VH has remained stable, with 20 % carried out this way [13,25–27]. The decrease in VH may well reflect a lack of scientific approach in choosing the route of hysterectomy. Unfortunately, surgeons all too often choose a route based on their own personal preference, rather than appealing to the evidence contained within the Cochrane database of systematic reviews on surgical approach to hysterectomy for benign gynaecological disease [1,7]. It is a common perception that the decreasing VH rate, sacrificed in favour inof LH, may be at least partially attributed to the impact of the industry that manufactures the laparoscopic equipment.

The trend in reduced rates of VH is concerning, in parallel with the fact that many residents leave residency programs without adequate proficiency in performing VH. Recent literature suggests that proficiency is achieved after 21–27 cases of VH during residency [25,28]. However, the current minimum requirement for VH in the USA residency programs is 15 cases, and only 5 cases during a four-year residency program in South Africa. This number of cases may provide exposure but is certainly not sufficient to ensure proficiency in performing VH.

Adequate training during residency and sufficient exposure to VH are vital components of the strategy to increase the prevalence of VH. Other factors that are considered prerequisites for a successful VH include vaginal accessibility, together with the size and shape of the uterus. The confirmation of pathology confined or not to the uterus may also influence the choice in route of hysterectomy. The International Society for Gynecologic Endoscopy (ISGE) recently established evidence-based recommendations on the selection of woman with benign uterine pathology who can undergo safe VH [29]. In Fig.1, an algorithm is reproduced from this ISGE publication, guiding the selection [29].

With the adoption of evidence-based practical guidelines and adequate surgical education, the proportion of hysterectomies performed vaginally can be increased and would lower the cost and complication rate [30–35]. For this reason, ISGE decided to introduce evidence-based practical guidelines on how VH for a non-prolapsed uterus should be undertaken.

Material and methods

The ISGE Task Force for VH for the non-prolapsed uterus defined key clinical questions (Table 1) regarding the surgical technique, which led the search of Medline/PubMed and the Cochrane Database. English-language articles, published from 1997 to 2019, including original works and previous reviews, were analysed. Using the GRADE approach (http://www.gradewor-kinggroup.org; Table 2), for each clinical question, we graded the available information by the level of evidence. The recommendations were developed through multiple cycles of literature analysis and expert discussion. The ISGE Ethical Committee ruled that approval was not required for this study.

Results

An inadequate number of randomised controlled trials (RCTs), systematic reviews, and meta-analyses are currently available to guide surgeons with respect to the VH procedure. Expert opinion has to be taken into account. The experience of surgeons with high case volumes serve as an important point of reference. The procedure presented below is a 10-step approach that is applicable in most cases of VH for benign conditions and a non-prolapsed uterus. Six recommendations on surgical steps for VH, including two grade IB and four grade IC were established (Table 3).

Preoperative considerations

The preoperative discussion should include an informed consent specifically documenting the risks and benefits of planned hysterectomy and the removal/conservation of the ovaries, expected outcomes and alternatives. Documentation that future fertility is not desired and pregnancy test are required in premenopausal women.

Preoperative evaluation of of the patient's general health status is fundamental in order to obtain a satisfactory outcome after

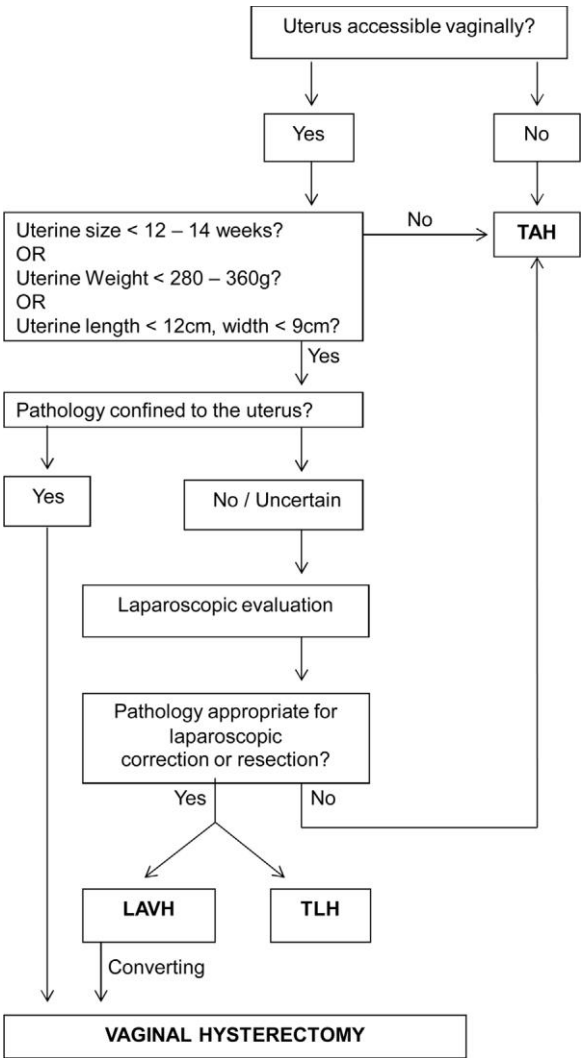

Fig. 1. Determining the route of hysterectomy for benign disease (reproduced with permission from [29]). *Abbreviations'*, LAVH, laparoscopic-assisted vaginal hyster- ectomy; TAH, total abdominal hysterectomy; TLH, total laparoscopic hysterectomy.

surgery. Cervical cancer screening should be up to date. It is important to evaluate the patient for anemia and correct it when existent. The risk factors associated with venous thromboembolic events should be assessed, allowing appropriate prophylaxis to be chosen.

Antibiotic prophylaxis

As indicated by other specific guidelines, all women undergoing vaginal hysterectomy should receive antibiotic prophylaxis (grade IC); cephalosporins (2nd or 3rd generation) and metronidazole are of proven value for vaginal hysterectomy (https://elearning.rcog.org.uk//preparation-patient-theatre/practical-points/antibiotic-prophylaxis/antibiotic).

Positioning the patient

After appropriate general or regional (spinal) anaesthesia is completed, the patient is placed in the dorsal lithotomy position with buttocks protruding slightly beyond the edge of the table with her feet in stirrups The lateral aspects of the legs should be clear of the stirrups to avoid pressure on the peroneal nerve.

Obesity should not be considered as a contraindication to VH. Obese and morbidly obese (BMI > 35) patients who undergo hysterectomy are at an increased risk of suffering complications such as pulmonary compromise, venous thrombosis, wound infection, and wound dehiscence. In practice, irrespective of the BMI, abdominal hysterectomy should be taken as an undesirable route for obese patients. Vaginal hysterectomy, where feasible, may be considered the primary route for hysterectomy in even morbidly obese woman [13]. However, in obese and morbidly obese (BMI > 35) women, it is advisable to apply a super flexion position (Fig. 2A). Anatomically, this position makes the uterus descend downward and fall backward, bringing the cervix closer to introitus. This may also facilitate bilateral salpingo-oophorectomy or an ovarian cystectomy, where this is needed [36].

After the skin and vaginal area are prepped in a habitual fashion, the urinary bladder is emptied with a metallic urinary catheter. Alternative indwelling Foley catheter can be inserted. A careful and completed bimanual examination must then be performed to confirm the degree of physiological or normal uterine descent, and the width of the vaginal outlet.The cervix is exposed by placing a weighted posterior retractor or the blade of the Auvard speculum. A small right angle retractor (Wertheim angle retractor) may be used to elevate the anterior vaginal wall. Two vulsellums are then utilized to grasp the anterior and posterior lips of the cervix and pulled into the vaginal introitus (Fig. 2B). The vulsellum is placed on the anterior lip of the cervix, upside down, so that instead of the instrument being concave upwards, it is concave downwards. The second vulsellum is placed on the posterior lip of the cervix with the instrument being concave upwards. While traction on the cervix downward is applied, massaging the uterosacral and cardinal ligaments bilaterally, especially on the left, may facilitate further descent [37].

Incision of the vaginal wall

While downward traction is applied with the vulsellum, a circular incision around the cervico-vaginal junction is performed (recommendation grade IC). The level of the incision is critical to find the correct plane of dissection between the bladder and lower uterine segment. The point of attachment of the vaginal mucosa to the cervix can be demonstrated by moving the cervix up and down. The incision should be made at the border between the smooth cervical mucosa and the vaginal rugae (Fig. 2C). An incision above the border of the cervix and vaginal rugae can lead to bladder injury and unnecessary bleeding, whereas if the incision is below the border, incision of the cervix may cause bleeding. It is

Table 1
Vaginal hysterectomy – key clinical questions.

Question 1:	Circular or V incision of the vaginal wall when performing VH for non-prolapsed uterus?
Question 2:	Clamping and cutting the uterosacral and cardinal ligaments before or after getting access into anterior and posterior peritoneum?
Question 3:	Detaching the bladder before or after opening the posterior peritoneum?
Question 4:	Closure or not of the peritoneum following VH?
Question 5:	Vertical or horizontal closure of the vaginal vault following VH?
Question 6:	To insert or not vaginal plug following VH?

Abbreviation: VH, vaginal hysterectomy.

Table 2
GRADE approach – grading of recommendations, risk/benefit and quality of supporting evidence.

Grade of recommendation	Risk/benefit	Quality of supporting evidence
1A. Strong recommendation, high quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
1B. Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
1C. Strong recommendation, low quality evidence	Benefits appear to outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.
2A. Weak recommendation, high quality evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
2B. Weak recommendation, moderate quality evidence	Benefits closely balanced with risks and burdens, some uncertainly in the estimates of benefits, risks and burdens.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
2C. Weak recommendation, low quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.

Table 3
The ISGE recommendations for vaginal hysterectomy technique.

Recommendation	Grade of recommendation
A circular incision at the level of cervico-vagina junction is recommended	Grade IC
The posterior peritoneum should be opened first	Grade IC
Clamping and cutting the uterosacral and cardinal ligaments before or after getting access into anterior peritoneum is recommended	Grade IC
Routine closure of the peritoneum during VH is not recommended	Grade IB
Vertical or horizontal closure of the vaginal vault following VH is recommended	Grade IC
To insert a vaginal plug following VH is not recommended	Grade IB

important for the incision to be deep enough reaching the pubo-cervical fascia which appears at this level as a white or pale grey area. The vaginal mucosa is circumferentially pushed up, away from the incision, with the use of a swab-covered index finger. This is done all the way up to the peritoneal vesico-uterine fold, anteriorly and posteriorly, far away up to the insertion of utero sacral ligament to the cervix.

The blade of the Wertheim angle retractor is placed under the vaginal mucosa and the bladder. Then, with strong traction on the cervical vulsellums downward, and counter traction with the retractor lifting up the anterior vaginal wall, the proper plane of dissection between the bladder and the cervix is found. This manoeuvre aids to identify the peritoneal vesico-uterine fold or anterior peritoneum, which appears as a pearly-white transverse line across the lower uterine segment lying on the wide V-shaped, shiny serosal surface of the uterus. Circular incision around the cervico-vaginal junction had been proposed by Sheth and others [38–47].

The anterior and posterior peritoneum are preferentially opened before the clamping and the cutting of the uterosacral and cardinal ligaments. This optional opening of the anterior or vesico-uterine peritoneum after clamping and cutting the utero-sacral and cardinal ligaments or the uterine vessels has been proposed by J. Cohen and others [37–42]. In some circumstances, when it is not feasible to enter the anterior peritoneum, before clamping and cutting the uterosacral/cardinal ligaments, it is worthwhile to detach the uterosacral and cardinal ligaments from their attachment, once the vaginal mucosa and the bladder have been mobilised. This can facilitate further descent of the uterus and assist with the identification and opening of the bladder peritoneum.

Opening the posterior peritoneum

Once a circular incision around the cervico-vaginal junction is made and the vaginal mucosa is pushed away, the posterior peritoneum is opened first (recommendation grade IC).The vulsellums holding the cervix are pulled upwards by the assistant. The peritoneum between the two utero-sacral ligaments (USLs) is grasped with artery forceps and opened with curved Mayo scissors (Fig. 2D). The scissors are then introduced into the pouch of Douglas. With the blades inside the peritoneal cavity, the scissors are opened and the blades withdrawn in the opened position so that the peritoneum is being cut by the back of the blades of the open pair of scissors, as they are being withdrawn. With the index finger into the pouch of Douglas, the posterior aspect of the uterus is palpated. Fibroids or adhesions may be identified at this point, together with the size and mobility of the uterus. The blade of the Auvard forceps or Sims speculum is introduced into the peritoneal space (pouch of Douglas). A large swab can be inserted into the posterior pouch, preventing small bowel and omentum entering the operating field. This swab keeps the rectum away. Since one third of the inserted swab is left hanging outside the vulva, this will not have any risk of leaving it behind. When the upper half of the

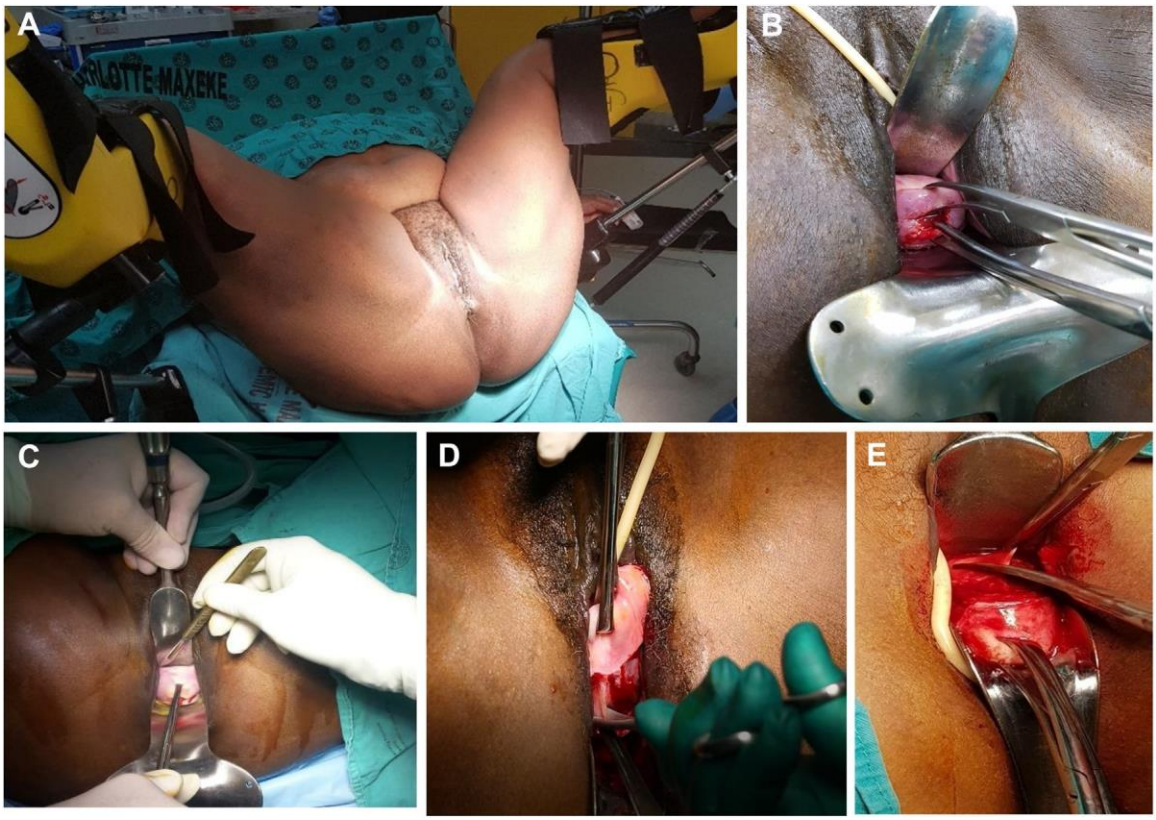

Fig. 2. Vaginal hysterectomy step 1 - 4. A, Positioning the patient(dorsal lithotomy super flexion position of a obese patient). B, Grasping the anterior and posterior lips of the cervix. C, Incision of the vaginal wall. D, Opening posterior peritoneum. E, Opening anterior peritoneum.

swab, which is in POD, is bloody it can be replaced with another swab.

It is necessary to open the posterior peritoneum first in some cases, such as previous caesarean sections or cases of anterior fibroids, as the anterior peritoneum may be difficult to be opened [37–45]-. In such circumstances, the index finger is introduced behind the uterus over the fundus of the uterus and the vesico-uterine peritoneum is identified and opened.

Bladder detachment from the uterus and anterior peritoneum opening

With the blade of the Wertheim angle retractor under the vaginal mucosa and bladder, the bladder is pushed up, with pressure, close to the uterus. As downward traction is applied with the vulsellums and counter traction upwards with the blade of the Wertheim angle retractor, the bladder will be separated from the uterus until the utero-vesical fold is exposed and the anterior peritoneum is identified. Exposure of the anterior peritoneal (utero-vesical) pouch is the most crucial step during VH. This is recognised as a white or pale area, owing to the double layer of peritoneum. The peritoneum is grasped with artery forceps or toothed dissecting forceps and opened with curved Mayo scissors (Fig. 2E). The scissor points must be angled towards the uterus to prevent accidental opening of the bladder. The blade of the Wertheim angle retractor is placed into the peritoneal cavity, separating the bladder from the uterus. Mild traction of this retractor not only holds the bladder out of the operating field, but also increases the distance of the ureters from the uterus. In our technique, entrance into the anterior and posterior cul-de-sac is established before clamping and cutting the uterosacral/cardinal ligaments, and definitely before clamping and cutting the uterine vessels. This facilitates the successful vaginal removal of the non-prolapsed uterus, and is associated with less bleeding and the prevention of potential injury to the bladder and/or ureters anteriorly, as well as to the rectum and small bowel posteriorly. In extremely rare situations where, access into the vaginal is limited (i.e. nulliparous women), VH can be done well without clamps by using pedicle sealing devices or without using clamps – so-called clamplessly – by using the ligature technique [13,38]

Dissection of the utero-sacral ligaments and cardinal ligaments

It is believed that the utero-sacral ligaments (USLs) and the cardinal ligaments (CLs) may provide apical support of the upper vagina and the uterine cervix. Their dissection can be performed before or after getting access into the anterior peritoneum (recommendation grade IC). Although both ligaments are located in different anatomical planes and directions, they are clamped together. This is done in a specific way: the cervix is pulled toward the operator and in the contralateral direction with the vulsellums. A curved Maingot clamp or similar clamp is placed in the posterior *cul-de-sac* with one blade underneath the USL/CL complex and the opposite blade over the USL/CL complex. The clamp is placed perpendicular to the long axis of the uterus, next to the uterine cervix, so that some tissue of the cervix is included in the clamp. It is important that the clamp is not placed laterally to the cervix because the cardinal and uterosacral ligaments lie at the lower end of the broad ligament, below the uterine artery, and are pierced by the ureter, which lies in the ureteric canal lateral to the artery. Both anatomical structures (USLs/CLs) are cut and ligated with 0 or 2.0 delayed absorbable suture, using a full-length suture with the needle attached (Fig. 3A–C). These sutures are not cut but clipped

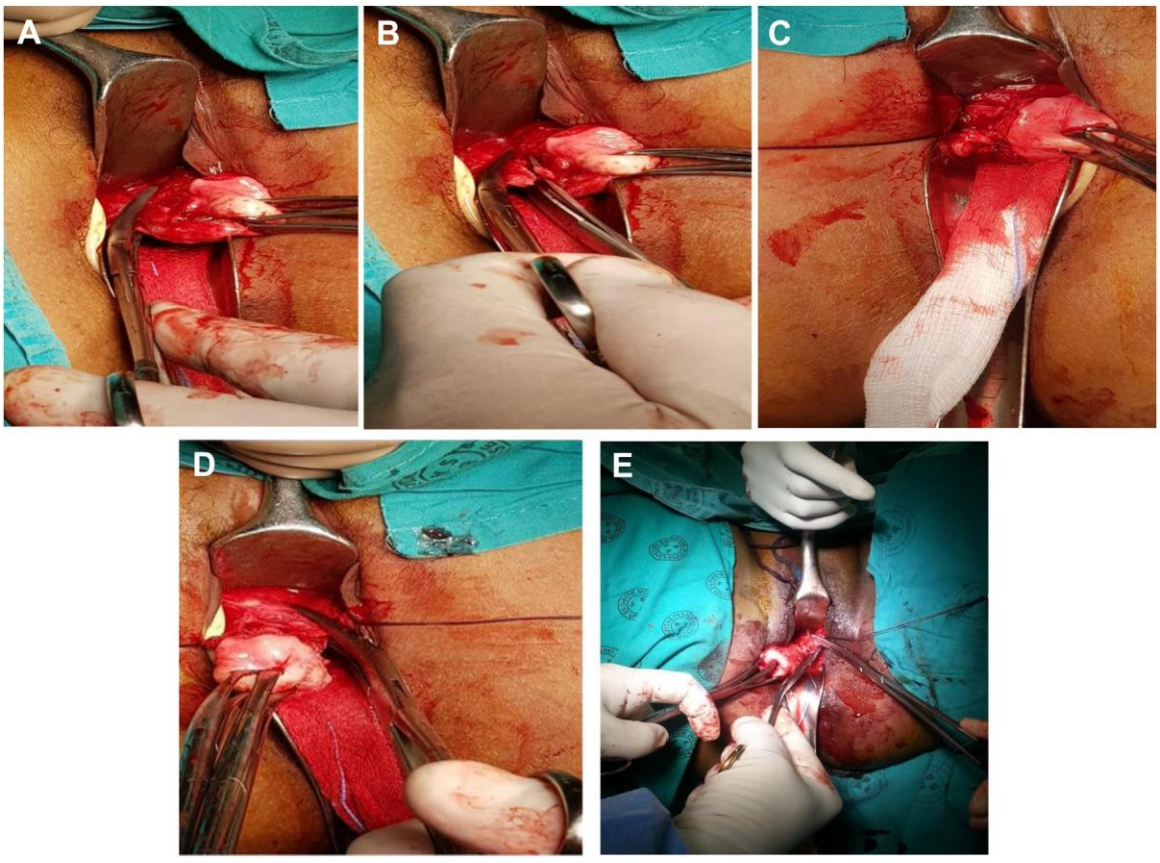

Fig. 3. Vaginal hysterectomy step 5 and 6. A – C. Dissection of the utero-sacral and cardinal ligaments. D and E. Clamping, cutting and ligating the uterine arteries.

to the covering drapes. The procedure is repeated on the contralateral side. The taking of these pedicles facilitates further descent of the uterus. The two sutures, with the needles attached will be used for closure of the vault to support the vault and avoid vault prolapse.

In patients with previous caesarean sections, or who present with previous inflammatory disease, endometriosis or anterior uterine wall fibroids, the anterior pouch, may be difficult to define. In such circumstances the index finger can be passed over the uterine fundus or broad ligament to define the anterior pouch. As described above, exposure of the anterior peritoneal (utero-vesical) pouch can be performed after the USLs/CLs are detached from their attachment, facilitating further descent of the uterus that makes the entry into the anterior peritoneal cavity easier. If it is still not possible to enter the space, we advise to make use of the uterocervical broad ligament space, described by Sheth [43]. In patient's with previous caesarean section the central 3/5 of the uterocervical surface is likely to be adherent to the bladder anteriorly and usually the bladder, the lateral 1/5 on both sides, lies freely on the cervico-uterine surface.The surgical technique had been described as follows: during VH, after the vaginal mucosa is incised push away the bladder with the assistance of the Wertheim angle retractor, the dissection is made laterally, first by scissors between the cervix and the bladder to enter the uterocervical space making room for the finger to follow, then insinuating upward and laterally beyond the lateral uterocervical border to enter into the continuing space between the two leaves of the broad ligament. The space is thus entered by sharp and blunt dissection and is gradually enlarged by the finger. After reaching the area between the uterocervical surface posteriorly and the bladder anteriorly and using gentle traction medially with Babcock forceps on the free bladder, assisted by sharp and blunt dissection, the bladder is separated from the uterocervical surface.

Clamping, cutting, and ligating the uterine arteries

Both uterine arteries are clamped, cut, and ligated. The uterine vessel pedicle, which contains the uterine artery and vein, and the broad ligament peritoneum anterior and posterior to these vessels, is clamped, cut, and ligated with a 0 or 2.0 delayed absorbable suture (Fig. 3D and E). Opening of the vesico-uterine peritoneum after clamping the uterine vessels, as recommended by Stark [45] and others [38,41,42], may lead to the injury of the bladder and the ureters if an inexperienced surgeon has not taken great care to mobilise the bladder well and to retract it well with the ureters.This emphasises the need for good early identification and mobilisation of the bladder. Routine opening of the vesico-uterine peritoneum after clamping the uterine vessels should be avoided. However, in rare circumstances, when the anterior peritoneal site cannot be reached earlier, careful bilateral severance of the USLs/CLs, vesico-uterine ligaments, and uterine vessels will allow the anterior peritoneal reflection provided the bladder is retracted laterally and superiorly away from the uterus, with the Wertheim angle retractor placed between the uterocervical surface and the bladder [43–47].

Dissection of the upper part of the uterine support

The remaining portion of the broad ligaments attached to the uterus (containing the round and ovarian ligaments, the proximal

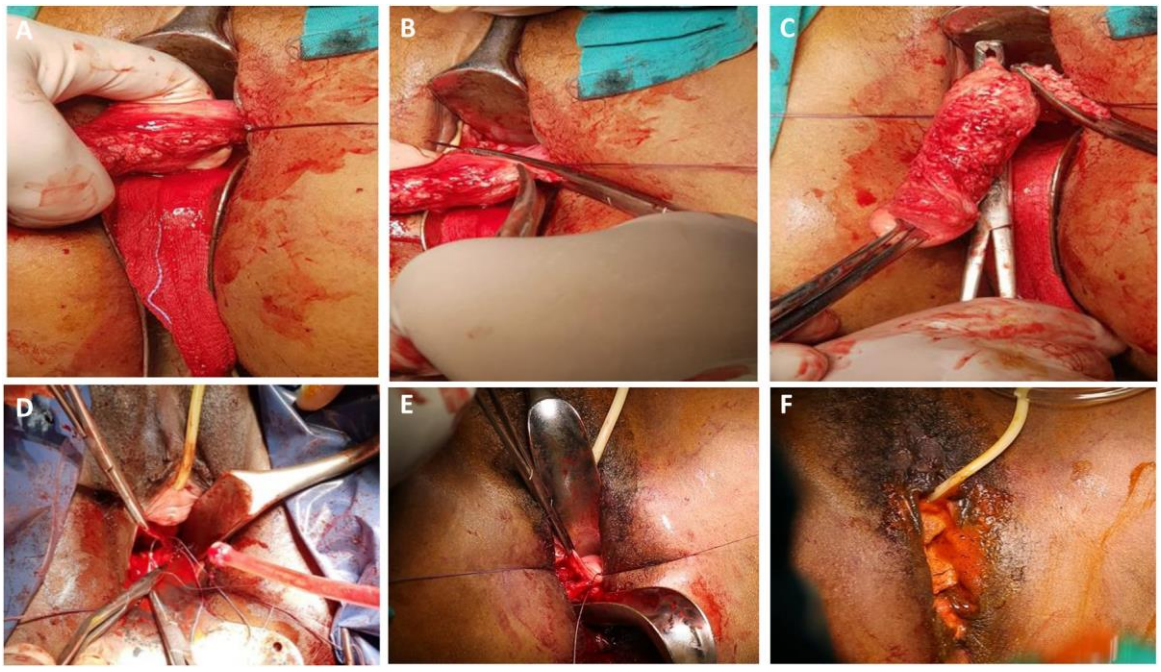

Fig. 4. Vaginal hysterectomy step 7 - 10.A – C. Dissection of the upper part of the uterine support.D. Closure of the peritoneum. E. Closure of the vaginal vault.F. Vaginal plug insertion.

part of the fallopian tube and the blood vessels) is then clamped, cut, and ligated bilaterally. The Maingot clamp or equivalent should be placed as close to the uterine fundus as possible. The uterus is then detached using curved scissors, such as Mayo scissors or a scalpel if preferred (Fig. 4A-C). The pedicles are tied separately and should not be tied together. As such, we disagree with Stark [45] and Bina [44], who advised to ligate these pedicles to each another, as we have found that tying the pedicles together can bring the ovaries into the pouch of Douglas and thereby lead to severe deep dyspareunia post-operatively.

Whether to remove the adnexa with or after removal of the uterus is a decision made as the most superior pedicles are approached. We prefer to remove the uterus, and then to attend to the adnexa. It is mandatory that the decision for the removal of the adnexa, particularly ovaries, be always taken well before surgery and performed only after required counselling and consent for the oophorectomy.

Once VH is performed, a moistened pack is gently placed in the pelvis to prevent bowel obscuring visualisation. When elongation of the Infundibulo-pelvic ligament permits, traction is placed on the ovary by grasping it with a Babcock clamp. A Maingot clamp is then placed across the Infundibulo-pelvic ligaments, and the ovaries and tubes are excised. Both a suture tie and a transfixion suture ligature can be placed on these pedicles to ensure they are secure. If this is not possible, then the transected tube and utero-ovarian ligament are pulled *en bloc* medially into the operating field until the round ligament is visualised. The round ligament is then clamped, cut and ligated. This allows further descent of the tubo-ovarian pedicle into the field, which can be clamped just above the tip of the ovary, and then ligated [46]. Sheth recommends, clamping the round ligament and tube separately, then dividing the tube and utero ovarian ligament on one side. After the round ligament has been divided on the opposite side the tube and ovary can be visualised and a curved clamp is used to clamp the infundibulopelvic ligament and mesosalpinx. A specially devised clamp by the author with a curve of 2 cm beginning at 1 cm from the tip fascilitates and accommodates the infundibular pelvic ligament efficiently [38]

Closure of the peritoneum

Closure of the peritoneum is recommended by some, as this can prevent prolapse of the fallopian tubes, which may be a cause of severe pain post-operatively and may also prevent bowel evisceration and posterior enterocoele formation postoperatively, after the VH [41,47]. Routine re-peritonisation is not supported [45,44,48]. Leaving the peritoneum open was recommended by the Royal College of Obstetrics and Gynaecology (RCOG) in its guideline No.15 in July 2002 with evidence level IB[49]. The advantage of leaving the peritoneum open is the prevention of vault haematoma by allowing free drainage of blood. If an enterocoele has to be prevented or repaired, it should be done at this stage.

Closure of the vaginal vault

Each angle is closed separately with the stitch and needle, held at the USL/CL complex on each side. Plicating the pedicles to the vaginal mucosa laterally offers additional support to the vaginal vault, preventing vault prolapse. Once the angles are secured, the closure of the vault is carried out with continuous interlocking sutures, using the same stitch bilaterally in a horizontal manner, such that the sutures meet in the middle (Fig. 4E). There is not sufficient data to support vertical or horizontal closure of the vaginal cuff [49]. Closure technique did not demonstrate any difference in operative time, blood transfusion, or cuff cellulitis [49–52]. Thus, the surgeon can choose vertical or horizontal suturing to close the vaginal cuff following VH (recommendation grade IC).

Urine catheter placement and vaginal plug insertion

There is insufficient evidence to support routine vaginal packing following vaginal hysterectomy. Three RCTs found no

apparent net benefits to vaginal packing for postoperative pain, satisfaction, bleeding, or infections. In addition, vaginal packing did not have an effect on the presence of a cuff haematoma six weeks after the surgery [53–55]. The recommendation against routine postoperative packing reaches grade IB, indicating that the risks of postoperative vaginal packing generally outweigh the benefits for most patients. For cases in which vaginal packing is chosen (Fig. 4F), an indwelling catheter must be inserted in order to allow urine drainage, and to avoid postoperative urine retention. Concurrent removal of the vaginal swab and catheter after 24 h is advisable. We recommend early removal of the bladder catheter to avoid febrile morbidity, facilitate faster mobilisation, and decrease length of hospital stay. However, there is not sufficient evidence supporting prolonged catheterisation [56,57].

Discussion

The gynaecologic literature for the last 30–40 years highlights the low percentages of hysterectomies performed vaginally, where there are not obvious contraindications. A lack of surgical experience and inadequate VH training during residency, due in part to a lack of standardised surgical technique, are major causes of this low VH rate among qualified gynaecologists. Additionally, a preference for LH over VH has emerged, driven perhaps by trade and the ever-increasing fascination with technology. Consequently, a generation of gynaecologists without the basic proficiency in VH has developed. Many patients who may have undergone an uncomplicated VH are thereby forced to undergo TAH or LH [58–60], and thus are denied the well-known patient benefits associated with VH (i.e. cost effectiveness, rapid recovery, etc.). It is evident from the literature review that this ratio can be changed in favour of VH, if focus is shifted from LH to VH. Brown, Kovac, Querleu and Sheth have reversed the ratio and performed hysterectomy vaginally for the non-prolapsed uterus in 79 %, 90 %, 77 %, and 84 % of cases, respectively, by using guidelines based on uterine size and formal decision algorithms [34,38,61,62]. Once qualified as a gynaecologist, surgeons should attend surgery at institutions where VHs are liberally or freely performed. The AAGL, recognising the inadequate training during residency and the lack of proficiency, recommends that surgeons without requisite training and skills required for the safe performance of VH should enlist the aid of colleagues who do, or should refer patients requiring hysterectomy to such individuals for their surgical care [11].

To combat the subjectivity involved in surgical decision-making regarding the method of hysterectomy clinical judgement is needed, particularly when decisions about the route of hysterectomy are to be made for benign uterine conditions. The physicians must evaluate the specific needs and expectations of each patient in order to arrive at the best management decision for each individual case. The International Society for Gynecologic Endoscopy (ISGE) has published evidenced-based recommendations on the selection of women for VH, to ensure that the most appropriate route of hysterectomy is undertaken [29]. Here, the ISGE introduces a follow-up set of guidelines, designed to provide a safe, standardised surgical algorithm for VH that can be easily taught in well-organised units. With clear guidelines in place, we hope to observe improved proficiency in VH and an increased preference for VH over more invasive routes of hysterectomy.

Conclusion

The vaginal route should be preferential for hysterectomy for the non-prolapsed uterus. In order to ensure that this is recognised and implemented, evidence-based guidelines for selecting the patient for VH, an algorithm tree and a standardised surgical technique are fundamentally important. Although further research in the field is absolutely needed, the ISGE provides recommendations based on published data and expert opinions for each step of the VH which should be performed in the same way and in the same order, aiming to train more residents to achieve proficiency in vaginal surgery.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Preferred and actual methods of hysterectomy: A survey of current practices among members of the South African Society of Obstetricians and Gynaecologists

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Background. Hysterectomy remains one of the most common operative procedures for benign uterine diseases. Total abdominal hysterectomy (TAH) constitutes the most common approach despite the advantages of minimally invasive hysterectomy (MIH).
Objectives. To explore the current opinion on hysterectomy choices amongst members of the South African Society of Obstetricians and Gynaecologists (SASOG), as well as the perceptions and potential barriers that may inhibit gynaecologists from offering MIH to their patients. **Methodology.** An anonymous survey designed to explore the preferences of practising obstetrician gynaecologists regarding the optimal hysterectomy procedure, and perceived barriers towards MIH.
Results. The average age of the respondents (N=152) was 45.7 years, with 88.2% having >5 years' experience in private practice. When asked about the preferred route of hysterectomy for themselves or their relatives, 46.2% chose vaginal hysterectomy (VH), 25.4% chose total laparoscopic hysterectomy (TLH), 15% chose laparoscopic assisted vaginal hysterectomy (LAVH) and 8.5% chose TAH. However, the most commonly performed hysterectomy procedure undertaken by the respondents in the last year was TAH. Only half of the respondents wished to increase their rate of VH and a lesser number to extend their laparoscopic hysterectomy rates.
Conclusion. Although the majority of the respondents preferred the minimally-invasive VH or TLH for themselves or their relatives, TAH remains the most common hysterectomy method among SA gynaecologists. This difference could present an ethical dilemma for the gynaecologist. The desire of a minority to change their approach to VH indicates the difficulty in changing attitudes and the need to promote VH as a technique within SASOG.

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Hysterectomy is one of the most common operative procedures for benign gynaecological diseases.[1] It can be performed abdominally, vaginally or laparoscopically, with or without robotic assistance. At present, total abdominal hysterectomy (TAH) constitutes the most common approach, despite the fact that vaginal hysterectomy (VH) or laparoscopic hysterectomy (LH) should be the preferred route based on their well-documented benefits.[2]

It is estimated that ~20% of women living in England and Wales will have undergone a hysterectomy before the age of 55 years. Most surgeons perform up to 80% of these procedures via the abdominal route.[3,4] The reason for this can be explained, in part, by personal preference, but is mainly due to a lack of training and experience, thus resulting in the surgeon's reluctance to perform VH. This is the case particularly in nulliparous woman in the presence of uterine enlargement, in women with previous gynaecological surgery or women who have undergone a previous caesarean section (CS). The above factors should not be considered as contraindications to performing VH.[5-7] In the USA, one in three women undergoes hysterectomy by the age of 60 years. Of these women, 22% have undergone VH. The introduction of LH increased the number of VH (if the uterus is removed by that route) to 33%; however, the additional 11% were exclusively performed laparoscopically and not without that assistance.[8] Despite the introduction of LH, 66.1% of the hysterectomies performed in the USA are open abdominal hysterectomies.[8] The benefits of VH are similar to those of LH, with minimal postoperative discomfort, less need for analgesics, shorter hospital stay and quicker return to normal daily activity compared with AH. There are also fewer postoperative complications and reduced hospital costs in VH than AH and even LH.[9-11]

Objectives

To explore the potential provider-related obstacles to offering less invasive hysterectomies, evaluate provider attitudes toward mode of access and inquire about provider-perceived contraindications to performing VH or LH.

Methods

The study was based upon a two-page, anonymous, electronic survey that was designed to explore practising gynaecologists' preferences regarding the optimal hysterectomy procedure for benign uterine conditions and the perceived barriers towards MIH. The survey included questions on demographic characteristics, preferred approach to hysterectomy, the approximate number of surgical cases per year and potential barriers or contraindications for performing VH or LH. A question enquiring whether surgeons have any intention of changing their approach to hysterectomy in the future was also included.

The survey was created on Survey Monkey (Wufoo, USA). The questionnaire was designed to be brief and easy to read, so that practising gynaecologists need not spend an excessive amount of time completing it. The questionnaire was validated by 12 local practising gynaecologists who assessed the clarity and confirmed the relevance of the questions. Thereafter, the survey was amended to its present form. The study was approved by the Ethics Committee of the University of Witwatersrand (ref. no. M150462).

A link to the survey was emailed to all practising gynaecologists who are members of SASOG. A second email was sent out 2 weeks after the initial email to those who had failed to complete the questionnaire. To complete the survey, participants were asked to click on the link and thereby be directed to the survey. Since the completion of the survey was done online and the results were stored in bulk on the Survey Monkey server, anonymity was preserved. Moreover, no personal information was requested by the survey itself, so the identity of the participants was not revealed.

Results

A total of 152 responses were received from SASOG members, corresponding to a 29.5% response rate. The majority of the respondents were male (56.7%). The average age of respondents was 45.7 years (Fig. 1), and 81.2% had >5 years' experience in private practice (Fig. 2). More than half (51.2%) of the respondents practised in Gauteng Province, 27% in the Western Cape and less than 10% elsewhere in South Africa (SA). The most commonly performed hysterectomy procedure that had been undertaken by the respondents in the last year was TAH, followed by VH and TLH (Table 1). However, when asked about the preferred route of hysterectomy for themselves or their relatives, 25.5% chose TLH, 15.1% chose LAVH, 46.2% chose VH and 8.5% chose TAH (Fig. 3). Therefore, almost all of the respondents were more likely to choose a minimally invasive approach to hysterectomy, including VH, for the patient benefits offered, as opposed to TAH (Fig. 4). Despite this, a preference for TAH in the daily practice of respondents was evident (Table 1).

The most significant reported barrier to performing VH was the lack of training during registrar time (31.0%), followed by a lack of surgical experience (15.9%), and then malpractice concerns and length of operating time (Table 2).

The most significant reported barriers to performing LH were lack of registrar training (29.3%) and inadequate surgical experience (21.4%), followed by hospital/patient cost, potential for complications and malpractice concerns (Table 3).

When asked about their ideal mode of access when performing hysterectomy, 23.8% of respondents answered TLH, 42.4% VH, 17.9% LAVH and 21.7% TAH (Table 4). The most significant contraindications for performing VH were adnexal mass, a history of endometriosis, lack of uterine descent, followed by previous pelvic inflammatory disease, narrow introitus, uterus larger than 12 weeks, and previous CS. When asked about their intention regarding changing the mode of access through which they perform hysterectomy, the majority of the respondents (66%) indicated that they would like their TAH rates to remain the same. Only 29.1% of respondents stated that they would like to decrease their rates of TAH; 52.4 and 41.6% indicated that they intended to increase their VH and TLH rates, respectively, while keeping the same number of LAVHs (Table 5).

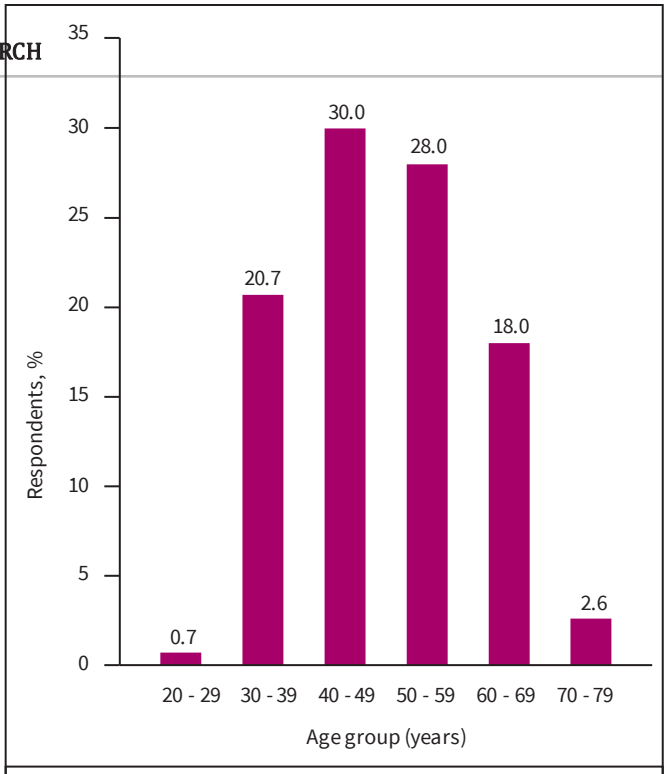

Fig. 1. Age distribution among respondents.

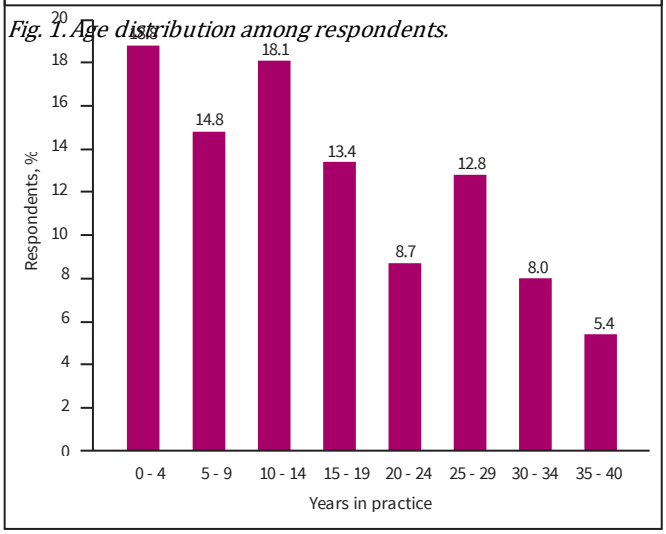

Fig. 2. Years in practice since completion of registration training.

Discussion

The majority of the respondents were between 30 and 69 years of age, with more than 5 years in practice since the completion of registrar training. All were members of SASOG. The survey was performed among practising gynaecologists with surgical experience in performing hysterectomy, with focus placed on their preferences between open and MIH, including VH. To the best of our knowledge, this was the first survey to evaluate barriers to performing less invasive hysterectomy in SA. The explicit aim of this study was to identify perceived barriers that deter practising gynaecologists from performing less invasive hysterectomy.

In our survey, we found discrepancies between practice patterns and physician preference. When practising gynaecologists were

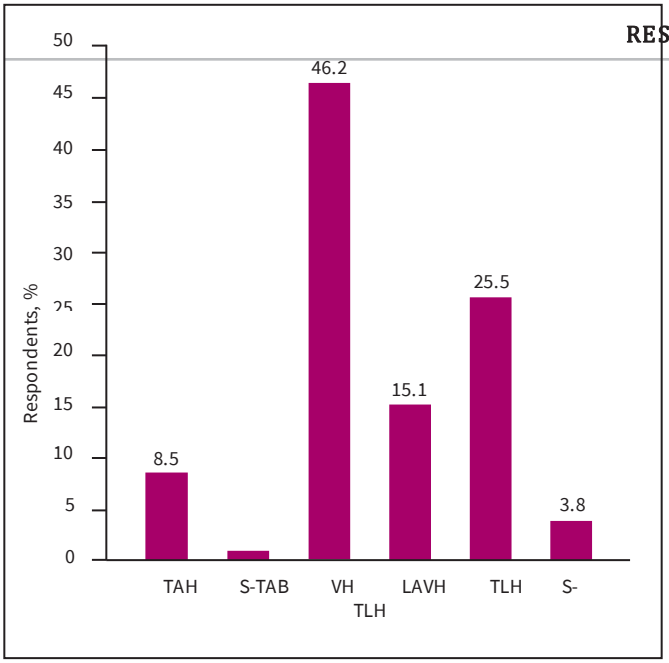

Fig. 3. Hysterectomy approach preferred for treatment of hypothetical non-malignant conditions to be applied to respondents or respondent's relatives. (TAH = total abdominal hysterectomy; S-TAB = subtotal abdominal hysterectomy; VH = vaginal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; TLH = total laparoscopic hysterectomy; S-TLH = subtotal laparoscopic hysterectomy.)

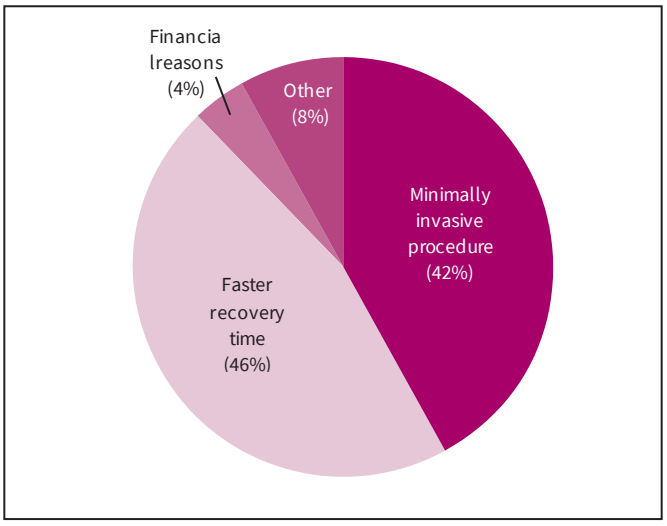

Fig. 4. The benefits of vaginal hysterectomy over total abdominal hysterectomy, as perceived by respondents.

asked to rank which hysterectomy approach they would prefer for themselves or their relatives, 86.8% would prefer a MIH, including TLH, LAVH and VH, compared with a TAH (8.5%). When asked which route of hysterectomy they considered the most ideal, 42.4% of survey participants chose VH, followed by TLH, TAH and LAVH. However, the reality of their practice is different, as TAH still makes up a large majority of hysterectomies performed by respondents over the course of a 1-year period. Our results are in agreement with Einarsson *et al.*[12] whose survey was performed in the USA among practising gynaecologists. While 8% of their respondents chose TAH as the preferred form of hysterectomy for themselves or their relatives, TAH remained the most commonly performed method.[12] This difference between preference and practice could present an ethical dilemma for gynaecologists if they are not able to offer potentially appropriate candidates the hysterectomy they would recommend for themselves or their relatives. This demonstrates that in spite of the well-documented patient benefits of MIH, including VH, LAVH and TLH, recognised by the respondents, the route of hysterectomy employed was still based on surgeon preference rather than patient benefits or condition. This seemed consistent with the findings of our study, as the participants expressed a desire to increase MIHs in their practice. They expressed a similar desire to increase their rates of LH (referring, in the context of this work, to both TLH and LAVH), as well as VH.

In the present study, the majority of the respondents indicated a reluctance to decrease the frequency of TAH and subtotal abdominal hysterectomy (S-TAB). These results are problematic in light of the fact that, although the majority of respondents recognised the benefits of MIH and, in particular, VH, they remained unwilling to change their approach. We explored the perceived barriers to performing VH in order to understand the discrepancy between attitude and practice. Lack of surgical experience and training during registrar time, followed by malpractice concerns and length of operating time, were the main perceived barriers. When practising gynaecologists were asked to rank the contraindications to performing VH, they prioritised adnexal mass, patients with endometriosis, patients with uterine fibroids, patients with previous CS, nulliparous patients, patients with previous laparotomies and lack of uterine descent.

Failure to achieve proficiency during training as a registrar was demonstrated in this survey as a severe obstacle to performing VH: lack of training and inadequate surgical experience featured in the majority of responses. Recent literature suggests that proficiency is achieved after 21 - 27 cases of VH are performed during residency.[13,14] However, the current minimum requirement for VH in USA residency programmes is 15 cases, and in SA, only 5 VH cases are required before sitting the final Fellow of the College of Obstetricians and Gynaecologists (FCOG) examination. This number of cases

Table 1. Frequency of various modes of hysterectomy access used by the respondents per year

Hysterectomy access	Number of procedures per year, *n* (%)						Total
	0 - 10	10 - 20	20 - 30	30 - 40	40 - 50	50 - 60	
TAH	42.3 (44)	25.0 (26)	11.5 (12)	5.8 (6)	5.8 (6)	9.6 (10)	104
S-TAB	94.4 (84)	3.37 (3)	2.3 (2)	0	0	0	89
VH	60.0 (60)	20.0 (20)	8.0 (8)	6.0 (6)	3.0 (3)	3.0 (3)	100
LAVH	91.9 (60)	5.8 (5)	2.3 (2)	0	0	0	86
TLH	79.5 (79)	8.4 (7)	6.0 (5)	3.6 (3)	0	2.4 (2)	83
S-TLH	95.0 (75)	2.5 (2)	1.3 (1)	0	0	1.3 (1)	80

TAH = total abdominal hysterectomy; S-TAB = subtotal abdominal hysterectomy; VH =vaginal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; TLH = total laparoscopic hysterectomy; S-TLH = subtotal laparoscopic hysterectomy.

Table 2. The most significant barriers to performing VH, as perceived by respondents

Obstade	Point scale,* *n* (%) 1	2	3	4	5	Total
Registrar training time	10 (13.5)	10 (13.5)	14 (18.9)	17 (23.0)	23 (31.1)	74
Operating time	26 (33.8)	24 (31.2)	15 (19.5)	6 (7.8)	6 (7.8)	77
Surgical experience	17 (20.7)	13 (15.9)	17 (20.7)	22 (26.8)	22 (15.9)	82
Malpractice concerns	25 (27.2)	19 (20.7)	23 (25.0)	17 (18.5)	8 (8.7)	92
Other	16 (21.6)	9 (12.2)	6 (8.1)	12 (16.2)	31 (41.9)	74

*Scale 1 - 5, where 1 represents the least significant barrier and 5 represents the most significant barrier.

Table 3. The most significant barriers to performing laparoscopic hysterectomy, as perceived by respondents

Obstade	Point scale,* *n* (%) 1	2	3	4	5	6	7	8	9	Total (*n*)
Registrar training time	9 (12.0)	4 (5.3)	4 (5.3)	5 (6.7)	5 (6.7)	4 (5.3)	6 (8.0)	16 (21.3)	22 (29.3)	75
Operating time	10 (12.5)	12 (15.0)	11 (13.8)	9 (11.3)	7 (8.8)	8 (10.0)	6 (7.5)	10 (12.5)	7 (8.8)	80
Surgical experience	7 (8.3)	10 (11.9)	9 (10.7)	4 (4.8)	6 (7.1)	6 (7.1)	9 (10.7)	15 (17.9)	18 (21.4)	84
Technical difficulties	2 (2.4)	2 (2.4)	13 (15.7)	15 (18.1)	12 (14.5)	15 (18.1)	14 (16.9)	7 (8.4)	3 (3.6)	83
Hospital/patient costs	9 (11.4)	9 (11.4)	8 (10.1)	12 (15.2)	12 (15.2)	8 (10.1)	9 (11.4)	6 (7.6)	6 (7.6)	79
Potential complications	1 (1.3)	7 (8.8)	6 (7.5)	15 (18.8)	21 (26.3)	12 (15.0)	10 (12.5)	4 (5.0)	4 (5.0)	80
Equipment availability	9 (10.1)	10 (11.2)	16 (18.0)	7 (7.9)	13 (14.6)	12 (13.5)	13 (14.6)	2 (2.3)	7 (7.9)	89
Malpractice concerns	4 (4.7)	18 (20.9)	6 (7.0)	7 (8.1)	8 (9.3)	10 (11.6)	13 (15.1)	13 (15.1)	7 (8.1)	86
Other	19 (31.7)	3 (5.0)	5 (8.3)	1 (1.7)	1 (1.7)	2 (3.3)	2 (3.3)	9 (15.0)	18 (30.0)	60

*Scale 1 - 9, where 1 represents the least significant barrier and 9 represents the most significant barrier.

Hysterectomy access	1	2	3	4	5	6	Total (*n*)
TAH	20 (21.7)	16 (17.4)	23 (25.0)	9 (9.8)	12 (13.0)	12 (13.0)	92
S-TAB	5 (5.9)	9 (10.6)	16 (18.8)	14 (16.5)	15 (17.7)	26 (30.6)	85
VH	39 (42.4)	26 (28.3)	14 (15.2)	5 (5.4)	4 (4.4)	4 (4.4)	92
LAVH	15 (17.9)	16 (19.1)	13 (15.5)	30 (35.7)	4 (4.8)	6 (7.1)	84
TLH	20 (23.8)	10 (11.9)	14 (16.7)	8 (9.5)	17 (20.2)	15 (17.9)	84
S-TLH	3 (3.5)	7 (8.1)	6 (7.0)	12 (14.0)	30 (34.9)	28 (32.6)	86

Table 5. Respondents' intended changes regarding the mode of access exploitation when pursuing hysterectomy

Hysterectomy access	Change, *n* (%) To increase	To decrease	To remain unchanged	Total
TAH	5 (4.9)	30 (29.1)	68 (66.0)	103
S-TAB	4 (4.1)	33 (34.4)	59 (61.5)	96
VH	54 (52.4)	3 (2.9)	46 (44.7)	103
LAVH	40 (42.5)	9 (9.6)	45 (47.9)	94
TLH	40 (41.6)	9 (9.4)	47 (49.0)	96
S-TLH	13 (14.0)	22 (23.7)	58 (62.3)	93

TAH = total abdominal hysterectomy; S-TAB = subtotal abdominal hysterectomy; VH =vaginal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; TLH = total laparoscopic hysterectomy; S-TLH = subtotal laparoscopic hysterectomy

provides exposure, but definitely cannot ensure proficiency in performing VH. The American Association of Gynecologic Laparoscopists (AAGL), recognising the insufficient training during residency and the benefits offered by VH as compared with other

TAH = total abdominal hysterectomy; S-TAB = subtotal abdominal hysterectomy; VH = vaginal hysterectomy; LAVH = laparoscopically assisted vaginal hysterectomy; TLH = total laparoscopic hysterectomy; S-TLH = subtotal laparoscopic hysterectomy. *Scale 1 - 6, where 1 represents the most ideal option and 6 represents the last choice.

minimally invasive techniques to hysterectomy, has stated that 'surgeons without the requisite training and skills required for the safe performance of VH or LH should enlist the aid of colleagues who do or should refer patients requiring hysterectomy to suchindividuals for their surgical care'.[15]

The insufficient training in VH during residency results in a generation of gynaecologists unwilling to change their approach to hysterectomy. The reluctance among consultants to adapt to less invasive hysterectomy may have already affected the more recent generation of registrars, as one respondent in this study claimed that 'many consultants can't perform VH so can't train registrars in VH'. Considering the contraindications to performing VH mentioned by the respondents, one can draw the conclusion that in the absence of uterine descent or prolapse, all hysterectomies are done either laparoscopically or abdominally in patients who may have otherwiseundergone an uncomplicated VH.

The contraindications to VH mentioned above should not be an obstacle to removing the uterus vaginally, provided the uterine size does not exceed 12 weeks, the pathology is confined to the uterus

and there is adequate vaginal access. Many studies have shown that challenging these contraindications can lead to an increase in the numbers of VH performed.[4-6] Recently, the International Society for Gynecologic Endoscopy (ISGE) released evidence-based guidelines, which include recommendations on the selection of women in whom VH can be safely performed.[16]

The most significant reported barriers to performing LH were chiefly a lack of surgical experience due to inadequate training, followed by the risk of complications resulting in malpractice concerns. The operating time was also a source of unease among respondents. Regarding LH, the results of this survey were in agreement with those found among senior obstetrics and gynaecology residents by Einarsson *et al*,[17] which showed that residents are unable to attain proficiency in most advanced laparoscopic procedures, including LH, during their residency. In a survey performed in Canada, 93% of respondents selected the endoscopic approach as their preferred approach,[18] but, 38.7% of the respondents felt that they had not received adequate training during their residency to perform endoscopy in general.

A preference for minimally invasive techniques was also evident in the present study, where respondents considered VH, followed by LH, as the most ideal mode of access when performing hysterectomy. These results were in agreement with other large surveys among practising gynaecologists.[12,19,20] As such, a global trend can be seen, demonstrated in both the literature and by our own study, in which the attitude towards minimally invasive techniques to hysterectomy is positive, but a lack of proficiency due to inadequate training during registrar time deters gynaecologists from acting on their preferences.

While lowered VH rates may well reflect a switch to laparoscopic procedures,[3,4,8] our data indicate that the major cause of the decline in VH rates is a lack of training during registrar time, and experience.

Respondents favoured LAVH as their ideal mode of access when performing a hysterectomy, whereas the vaginal route was considered the most ideal for hysterectomy. This preference for LAVH was also observed in a survey conducted to assess modes of access in performed hysterectomies in Germany.[21] These results may suggest that the laparoscopic technique was considered an aid to VH rather than a replacement for it. This is in agreement with a 2001 postal survey conducted in England among consultant gynaecologists that demonstrated that gynaecologists who performed many LHs had the highest VH rates, and predicted that VH would be further emphasised in years to come.[22] It may be that LAVH could serve as the vehicle for performing more VHs in the future.

It must be stated that our study had limitations as well as strengths. The first of its strengths lay in the fact that our survey took place among general gynaecologists, in the style of the majority of surveys published in the literature.[12,17-20] Secondly, to the best of our knowledge, it is the first national survey conducted among SASOG members to evaluate barriers to performing MIH. However, our study was limited by its low response rate, as only 29.5% of potentially eligible doctors opted to complete the survey. This level of response is not unusual for electronic surveys, and in particular for surveys of doctors,[23] for whom a lack of time and survey burden are well-documented impediments to participation.[24] Furthermore, we acknowledge the potential for bias: it is possible that the respondents may not be representative of the overall population of minimally invasive gynaecological surgeons in practice in SA, which may have adversely affected our results.

Despite these possible limitations, we consider our hypothesis supported by the data collected through our survey. Insufficient training during registrar time and limited surgical experience were perceived as severe barriers when considering less invasive approaches to hysterectomy, thereby demonstrating that registrar training and experience indeed affect a surgeon's approach to hysterectomy. Furthermore, our data revealed that a positive attitude toward less invasive techniques does not necessarily reflect the surgeon's reality. VH and thereafter LH were considered ideal approaches to hysterectomy; however, TAH remained the surgeon's preferred practice. This, in conjunction with the sustained high number of TAH still performed worldwide, serves as a major indication that barriers to performing less invasive hysterectomies need to be addressed. Additional training opportunities to increase the numbers of VH and LH (namely TLH and LAVH) were suggested by the surgeons who answered the survey, and may be necessary to ensure that surgeons are capable of operating in accordance with their ideal method.

Conclusion

For the SASOG members who participated in our survey, preferences for the routes of hysterectomy compared with their actual practice appear inconsistent. The large discrepancy between practice and preference indicates that the route of surgery is more dependent on the clinical preference of the gynaecologist than the medical condition. Strategies should be initiated to increase training opportunities during registrar years in MIH, especially VH. Guidelines for performing MIH should be put in place to help our colleagues perform more MIH, including VH, in accordance with their ideal preferences.

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Cost analysis of vaginal hysterectomy as compared to laparoscopic assisted vaginal hysterectomy for non-prolapse uterus in a tertiary institution in South Africa

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Abstract

Background: Many hysterectomies are now performed by laparoscopic assisted vaginal hysterectomy (LAVH)technique.To establish LAVH as a routine procedure remains controversial, partly because of concerns about the cost. We studied hospital charges and costof LAVH as compared to vaginal hysterectomy (VH) for non-prolapse uterus in clinically similar groups of patients

Study design: This was a cross-sectional analytic study, covering a period of two years. This study was undertaken at the Department of Obstetrics and Gynaecology of the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), to determinethe direct hospital costs between the two surgical techniques VH and LAVH respectively. Women admitted for hysterectomy for benign uterine conditions, were enrolled in the study. Criteria for inclusio n were uterine size less than 12 weeksgestation,width≤ 9 cm and length ≤ 14 cmon ultrasound examination. Clinical ovarian pathology and uterine prolapse were criteria for exclusion. Patients were recruited from the unit records and divided into two groups matched with respect to age, parity, and indications for hysterectomy. Vaginal hysterectomy was performed in 60 patients out of the 100 patients included in the study, and 40 patients underwent LAVH.

Results: All cases were successfully performed with no need to convert to the abdominal route. The time required for LAVH was significantly longer as compared to VH: 64,0 v 31,3 minutes respectively ($p<0.001$). The postoperative hospital stay days and opiate injections required were both not significantly different between the VH and LAVH groups.Longer operating time and ,as well as the expenses of the equipment to perform LAVH, were the main sources of additional cost in LAVH. The average hospital charges were significantly higher in LAVH as compared to VH ($p< 0.001$).

Conclusion: Both techniques offer the same benefits of shorter hospital stay, less analgesia needed, rapid mobilisation, and early discharge. However,VH wasfound to be least costly, mainly due to significant less operative time. LAVH is significantly costlier, mainly due to expensive laparoscopic devices and afore-mentioned long operation time.

Keywords: Benign gynaecological pathology, vaginal hysterectomy, Laparoscopic assisted vaginal hysterectomy, non-prolapse uterus, hysterectomycost.

Introduction

Hysterectomy is currently one of the most common operative procedures for benign uterine diseases performed in the world [1,2]. In a large scale surveys, 70- 80% of hysterectomies have been shown to be carried out via the abdominal approach, except when treating utero-vaginal prolapse, for which the vaginal route is generally preferred[3-12]. This latter indication accounts for about 10% of all hysterectomies conducted worldwide [12,13], The advantages provided by vaginal hysterectomy (VH)or laparoscopic hysterectomy (LH), either total laparoscopic hysterectomy (TLH) or laparoscopic assisted vaginal hysterectomy(LAVH)over abdominal hysterectomy (AH) include less postoperative pain, less need of analgesia, shorter hospital stay, more rapid recovery and return to daily activities, and reduced hospital charges [14-18] Additionally, intra-operative and post-operative complications reported with VH as compared with AH or LHare much less [19-21]. Despite the benefits offered by VH, the advent of laparoscopic approaches had little effect in reducing the rate of AHs. Burkett D *et al.* – assessing current trends in resident hysterectomy training – concluded that with the initiation of endoscopic approaches(LH) and robotic hysterectomy (RH), the VHs are underutilised [22]. Two studies based on data from the US in the mid-90s analysed the costs andcharges associated with VH and LAVH, and determined that VH appeared to be much cheaper than LAVH [23, 24]. This study intends to perform an evaluation of these costs and charges associated with VH and LAVH, in a tertiary institution in South Africa. This is in our understanding the first study of its kind to be performedin South Africa or even in the African Continent.

Materials and Methods

This is a cross-sectional analytic studythat took place at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). The study was approved by the Ethics Committee of the University of Witwatersrand(ref. Nr:M150462). CMJAH is a tertiary-level academic hospital, and a referral centre for the eastern and western areas of greater Johannesburg. The department of obstetrics and gynaecology is attached to the University of the Witwatersrand.All patients admitted between January 2015 and December 2016 for hysterectomy due to benign conditions, meeting the guidelines criteria (vaginally accessible uterus, uterine size $\leq$ 12 weeks of gestation or $\leq$280 g on ultrasound examination, pathology confined to the uterus) were included.According to the guidelines set by the unit, nulliparous women, women without uterine descent, women with fibroid uterus, women with previous pelvic surgery or caesarean section, and women with cervical dysplasia or pre-malignant conditions were also included. Women with utero-vaginal prolapse and adnexal pathology who underwent VH were excluded from the study.

Clinical baseline data that were evaluated included the patient's age, parity, the type of the procedure, the length of hospital stay, uterine weight, and the incidence of intra- and immediate post-operative complications. The costing was done from the provider's perspective (the hospital), and focussed on direct costs. Indirect costs included costs for laboratory investigations, medications not related to the procedure, drugs used after the operation for either analgesia or pain control and management of complications if any. These indirect costs or "ward charges" were not included in the costing. Only variable direct costs were included because fixed direct costs (e.g. capital costs, overheads) were assumed constant regardless of the type of procedure. The direct costs were defined as charges for operating time per minute on a subset of patients who had VH and LAVH and consumables used for the procedures, LAVH and VH only. The operative time was measure for each procedure, calculated as the time that elapse from the first cut to the closure of the abdominal incisions in cases of LAVH or to the closure of the vaginal vault in cases of VH.

The medical aid scheme rate corroborated with the private sector was used to determine the cost of operation time per minute. In this setting it was calculated as (R187.00 + R200.00 ÷2) hence giving a rand value of R193.50 or 15,3 USD. The price of disposable instruments used for the procedures were obtained from three different companies ((Johnson& Johnson Medical SA, Covidien-Medtronic SA and LigaSure TM) which supplied the hospital during the study period.

However, the costs that were discussed were estimates rather than exact figure and include only the differences in theatre time amongst the two procedures and the consumables used.

Professional fees, which included the amount paid to the surgeon, the assistant, the anaesthetist and the theatre staff during the procedure, were not included in the analysis, as this is a state-run facility with salaried employees. The hospital charges for VH and LAVH performed during the study period which include ward fees - from admission to discharge were not included in the analysis as there was not a significant differences in hospital stay and analgesia needed between the two procedures. The direct cost of the procedures VH and LAVH, which included operation time and consumables, will be shown in South Africa rand (ZAR) and US dollars (USD), based on the mean exchange rates during the study period, which was 1USD= 11,6 ZAR in January 2015 and 13,6 ZAR in December 2016,by the end of the study The mean exchange rates used to calculate the cost of disposables and extra operating time for LAVH was 1USD= 12, 6 ZAR .Consumables used to perform the two procedures namely, LAVH and VH will be discussed in the results. The vessel sealing device, Liga-Sure ^{TM} was used for all the LAVH. All the patients received prophylactic antibiotics.

Statistical analysis. Data were analysed with STATA V 14.1. Mean and standard deviation, median and IQR, and proportions were used to describe the socio-demographic characteristics and outcomes of the study participants. Continuous data, if normally distributed, were compared between LAVH and VH groups using the student t-test, otherwise a Mann-Whitney test was applied. For categorical data a Chi-square test was used to compare categorical variables between LAVH and VH groups. The results were considered to be statistical significant for a p-value <0.05.

Results

During the study period, four hundred seventy hysterectomies were performed in our department. Out of these 222 (47, 2%) underwent VH. 43 (9, 1%) of the VH have been accomplished with the aid of LAVH (Fig 1).Out of these, 100 patientsmeeting the inclusion criteria set by the unit and matching in respect to the age, indication, parity and uterine weight as reported by the department of histopathology were selected and analysed.It was imperative that the patients selected possessed sufficiently similar characteristics, in order to allow for sensible and reliable

comparisons to be made.There were no significant differences in age, uterus weight and parity between VH and LAVH patients. However, the indications were significantly associated with the type of hysterectomy performed (Table1). All cases included in the study were successfully performed (no intra- or immediate post-operative complications) and there was no need for conversion to open AH.

Average number of hospital stay days and opiate injections required were both not significantly different between the VH and LAVH groups. However, there was a significant difference between VH and LAVH operation time (minutes) with those who underwent LAVH hysterectomy needing more time 64 min v 31.3 minutes for VH, p-value<0.001 (Table2).

A summary of the key measures of resources used in the study can be found in Table 3. The mean cost of operation time was equivalent to193,50 ZAR or 15,3 USD per minute.The LAVH in our study took 32,7 minutes longer than VH; the total cost of extra theatre time needed to perform LAVH as compared to VH wasestimated to be 6327.45 ZAR. Themean cost of consumables regularly used by the unitwas estimated to be 12 046.09 ZAR. Considering the extra theatre time and the consumables used during LAVH, an amount of18373.54 ZAR or 1458.28 USD more was needed to perform LAVH as opposed to VH for the same indication and uterine weigh.

Discussion

The results of this study are in agreement with those of other studies [14-18] which,clearly demonstrate that VH is lesscostly , andprovides the same advantages as LAVH, namely less postoperative pain, less need of analgesia, shorter hospital stay,and a more rapid recovery and return to daily activities.Key measures used in this study to assess cost difference amongst the two procedures were related to operating time in theatre per minute, and the use ofconsumables during LAVH. Dorsey*et al.*, comparing costs and charges with three alternative techniques of hysterectomy --LAVH, AH and VH -- found that the mean total charges (facility charges plus professional fees) for the hospitalisation were much higher for LAVH as compared to VH ($p<0.001$) with the same clinical outcome [23]. Nehtat *et al.* --comparing also the costs and charges of LAVH, AH, and VH --found that the mean cost of performing LAVHas compared to VH was significantly higher ($p< 0.05$) [24]. A cost effectiveness analysis undertaken with the eVALuate study revealed that the vaginal approach was more cost-effective compared to the

laparoscopic route, primarily due to the use of disposable instruments in laparoscopy [15]. Furthermore, Sculpher *et al.* found that LH cost an average of $708 more than VH, per patient. With more than 500000 hysterectomies performed annually in the United States, and more than 100000 in the United Kingdom, the vaginal approach seems even more relevant in this time of economic strain [25]. Kovac *et al.* found that by using guidelines to assist clinical decision-making for hysterectomy, VH found to be feasible in 98.9% of the cases, with potential savings of 1.2 million USD could be obtained for every 1000 hysterectomies performed vaginally, as well as a reduction of 20% in complications associated with the procedure [26].

Our results are in agreement with the above mentioned studies demonstrating that VH is the less costly route for hysterectomy [4, 23-26]. The main sources of the cost difference between LAVH and VH in our study were related to the differences in operation time and the cost of consumables used during LAVH compared to VHwhich requires no additional specific materials. In our study, LAVH took 32,7 minutes longer than VH ($p<0.001$).Considering the extra theatre time and the consumables used during LAVH, an estimated amount of 18373.54 ZAR or 1458.22 USD more was needed to perform LAVH as opposed to VH for the same indication and uterine weigh (excluding the aforementioned professional fees).

We estimated that by opting to perform VH instead of LAVH in patients presenting with the sameindications and uterine weight, as much as 18.4 million ZARor 1.45 million USD, could be saved for every 1000 hysterectomies performed vaginally in South Africa. Choosing VH over LAVH has not been reported to affect hospital stay (ward fees) or drugs used during the immediate postoperative period and drugs given on discharge.When cost analysis wasundertaken for this study, VH found to be much cheaper than LAVH. Longer operating time, as well as the expenses of the equipment to perform LAVH, were the main sources of additional cost in LAVH.

Conclusion

LAVH is unlikely to be considered cost effectivewhen comparedto VH for women undergoing hysterectomy for the same indication and uterine weigh. All efforts should be directed to increase the numbers of VH among appropriately selected women, who today are operated in the main by the abdominal or laparoscopic approach despite VH serving as a viable alternative.

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Table 1. Patient characteristics, indications for hysterectomy and the weight of the uteri measured after the operation. Values are means (SD).

VH = Vaginal Hysterectomy

LAVH = Laparoscopic hysterectomy

	VH	**LAVH**	**P-value**
N	60	40	
Age, Median (IQR)	42.5 (37-46.5)	43 (36-46)	0.7480*
Uterus Weight {g}, Median (IQR)	65 (52-74)	57.5 (45.5-70)	0.2067*
Parity {n}, Mean (SD)	2.1 (0.9)	1.9 (1.1)	0.3541#
Indications, n (%)			
Adenomyosis	1 (2.5)	1 (1.7)	
HGSIL	27 (45)	15 (37.5)	
HGSIL/CPP	0 (0)	4 (10)	
HGSIL/MEN	2 (3.3)	0 (0)	
HGSIL/MFU	9 (15)	2 (5)	
HGSIL/MFU/PMB	0 (0)	1 (2.5)	
MEN	1 (1.7)	0 (0)	
MEN/MFU	3 (5)	7 (17.5)	
MFU	17 (28.3)	10 (25)	0.022+

*Mann-Whitney U Test; #Independent-T Test; +Fishers' Exact Test

Table2. Comparison of operation time, not including anaesthetic time between VH and LAVH post-operative course

	VH	**LAVH**	**P-Value**
N	60	40	
Operation time {min}, Mean (SD)	31.3 (4.6)	64 (10.1)	<0.001
Hospital Stay {days}, Mean (SD)	2.1 (0.32)	2.2 (0.46)	0.2925
Opiate injections required {n}, Mean (SD)	2.9 (0.28)	3 (0.64)	0.3752

Table 3. Estimated variable direct cost per LAVH vs. VH. Consumables price in ZAR

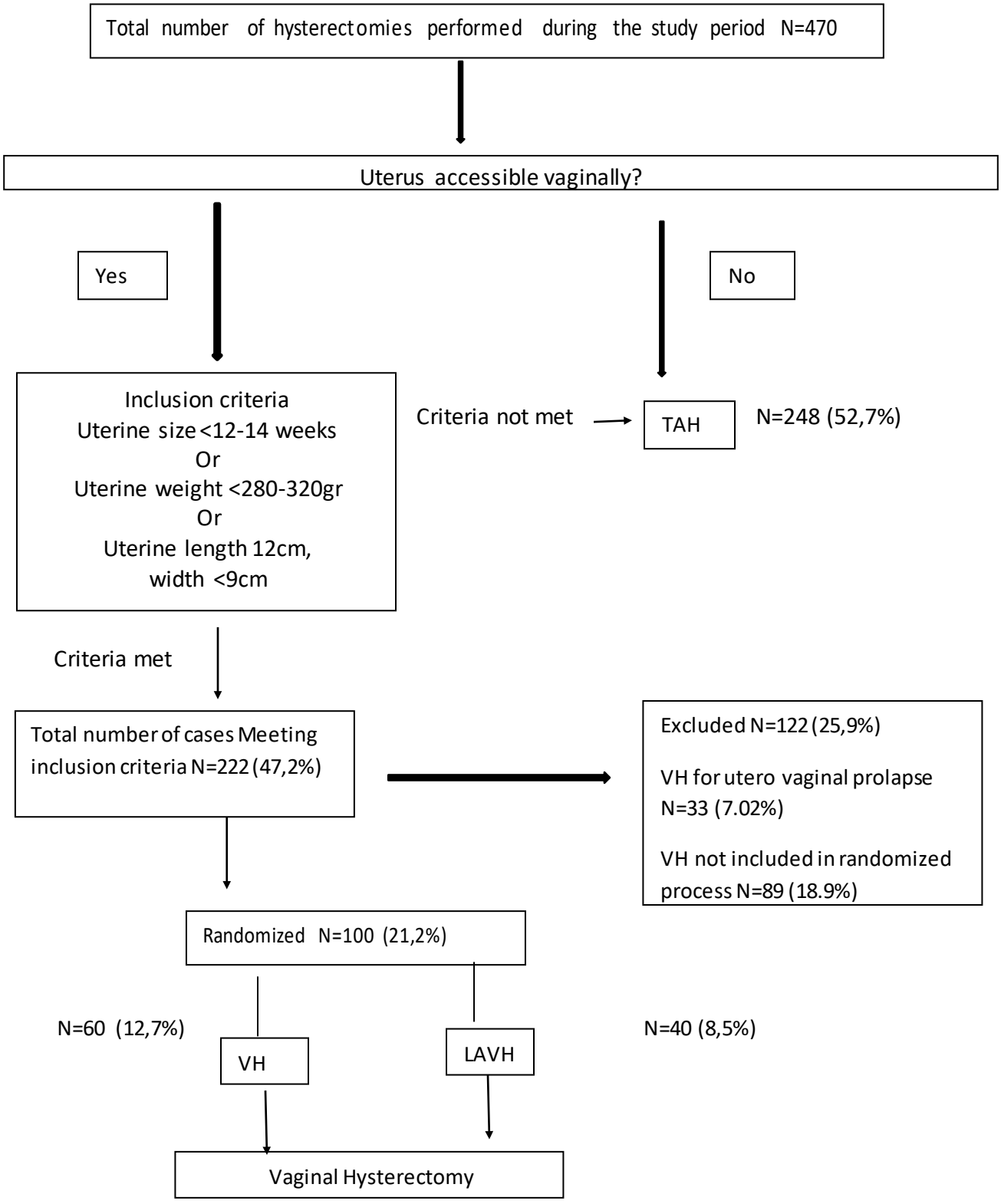
Resource items	**Estimated cost per procedure (ZAR)**		
	LAVH	**VH**	**Cost difference**
Surgical cost per mean operating time	12384,00 ZAR	6056,55 ZAR	6327,45 ZAR
Consumables used during procedures	12046.09 ZAR	No consumables	12046,09 ZAR
Suture material used[X]	258.10 ZAR	260.55 ZAR	2.45 ZAR
Pharmaceuticals used during surgery, during post-operative period and discharge *	N/A	N/A	
Ward charges*	N/A	N/A	
Scrap sister and theatre staff +	N/A	N/A	
Specialist Surgeon, assistant Surgeon, anaesthetist +	N/A	N/A	
Total			**18373,54 ZAR**

[X] Cost of suture materials used during the two procedures, LAVH and VH not included in the cost calculation as there were no significant differences

*Disposables used during the procedure are not included in the cost calculation

+ Professional fees were not included in the analysis, as this is a state-run facility with salaried employees.

Figure 1


Total number of hysterectomies performed during the study period N=470
Uterus accessible vaginally?
Yes
No
Inclusion criteria
Uterine size <12-14 weeks
Or
Uterine weight <280-320gr
Or
Uterine length 12cm,
width <9cm
Criteria not met
TAH
N=248 (52,7%)
Criteria met
Total number of cases Meeting inclusion criteria N=222 (47,2%)
Excluded N=122 (25,9%)
VH for utero vaginal prolapse N=33 (7.02%)
VH not included in randomized process N=89 (18.9%)
Randomized N=100 (21,2%)
N=60 (12,7%)
VH
LAVH
N=40 (8,5%)
Vaginal Hysterectomy

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Full length article

Formal institutional guidelines promotes the vaginal approach to hysterectomy in patients with benign disease and non-prolapsed uterus

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Surgical decision algorithm
Vaginal hysterectomy

ABSTRACT

Objectives: This study was undertaken at the Department of Obstetrics and Gynaecology of the Charlotte Maxeke Johannesburg Academic Hospital to determine if the use of formal guidelines and a standardised surgical technique would increase the rate of vaginal hysterectomy (VH) and result in an overall decline in open abdominal hysterectomy (AH).

Study Design: All women admitted between July 2001 and December 2014 for hysterectomy due to benign conditions, meeting the guidelines criteria (vaginally accessible uterus, uterus ≤ 12 weeks size or ≤ 280 gm on ultrasound examination and pathology confined to the uterus) were included. The surgical route was determined using the Unit surgical decision tree algorithm. In cases where the pathology was not confined to the uterus or success in VH was uncertain, laparoscopic assisted vaginal hysterectomy (LAVH) was performed. The VH procedures were performed by the residents in training, under the supervision of specialists with large experience in vaginal surgery. In addition to the patient characteristics and surgical approach to hysterectomy, length of hospital stay, intra-operative and immediate post-operative complications were also recorded and analysed.

Results: A year before the initiation of the study, the percentage of all VHs undertaken in the Department was 9.8 % (mainly performed for utero-vaginal prolapse). During the study period, 1143 vaginal procedures (1017 VHs and 126 LAVHs) were performed. The most common indications were cervical dysplasia, uterine fibroids, dysmenorrhoea or abnormal uterine bleeding, adenomyosis, endometrial hyperplasia and chronic pelvic pain. Introducing a formal clinical decision tree algorithm and a standardised surgical technique resulted in an increase in the rate of VH to 48.4 % and overall decline in open AH from 91.2%–51.6%. Thus, the VH/AH ratio increased from 1/9 at the beginning of the study (July 2001) to 1/1 by its end (December 2014). In all cases, VH was performed without the need to convert the vaginal to the abdominal route.

Conclusion: The use of institutional guidelines for determining the hysterectomy route and a standardised VH technique resulted in an increased number of performed VHs. This provided an essential opportunity for residents to acquire, improve and maintain the skills required to safely perform VH.

Introduction

Globally, hysterectomy serves as the most common treatment for benign uterine conditions [1,2]. Hysterectomy can be performed *via* the abdominal, vaginal, or laparoscopic route, with or without robotic assistance. The advantages provided by both vaginal and laparoscopic hysterectomy (VH and LH, respectively)

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over abdominal hysterectomy (AH) include less postoperative pain and need of analgesia, shorter hospital stay, more rapid recovery and return to daily activities, and reduced hospital charges and therefore cost [3–7]. However, VH is associated with fewer intra-operative and postoperative complications as compared with AH or laparoscopic hysterectomy (LH), either total laparoscopic hysterectomy (TLH) or laparoscopy-assisted vaginal hysterectomy (LAVH) [8–10]. Despite this, AH remains the chosen route for benign uterine conditions, worldwide. This preference is largely due to a lack of experience in VH, resulting in surgeons' reluctance to perform VH, especially in patients without uterine prolapse, ignoring the fact that a vast worldwide literature has demonstrated its applicability in benign diseases such as uterine fibroids, in those with previous laparotomies, caesarean sections, as well as in nulliparous women [11–16].

In spite of the benefits offered by VH, globally still 70–80% of hysterectomies have been shown to be carried out *via* the abdominal approach, according to all large-scale surveys, except when treating utero-vaginal prolapse [17–27]. This latter indication accounts for about 10 % of all hysterectomies conducted

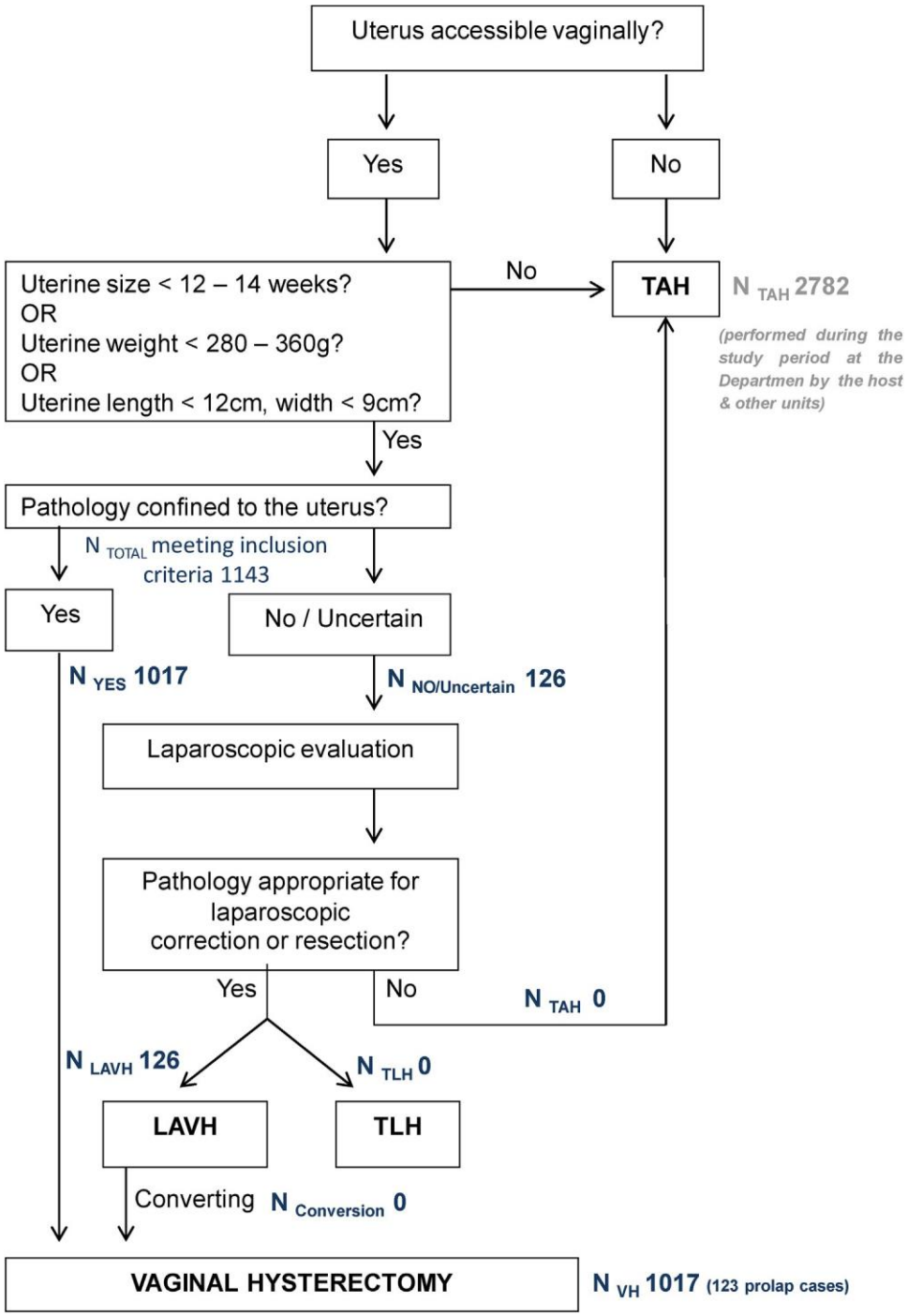


Fig. 1. Formal Unit decision algorithm used for determining the route of hysterectomy for benign disease (approach based on clinical examination and pelvic ultrasonography). N indicates the number of cases included during the study in each category. Abbreviations: LAVH, laparoscopically-assisted vaginal hysterectomy; TAH, total abdominal hysterectomy; TLH, total laparoscopic hysterectomy; VH, vaginal hysterectomy.

worldwide [27,28]. The rate of LH has been increasing, without a significant reduction in AHs. This increase in LH has thus been incurred at the expense of VH. Assessing current trends in resident hysterectomy training, Burkett *et al.* concluded that there is an increase in endoscopic approach, including robotic hysterectomy (RH), while VH is becoming inappropriately replaced and underutilised [29]. However, this highlights a fundamental problem currently facing clinical gynaecology, namely insufficient VH training/practice due to the inadequate experience of junior trainers in VH, and the consequent lack of appreciation of the benefits afforded by VH.

In this study, we investigated the possibility of increasing the number of VHs performed by residents – and thus the improvement of their proficiency in the procedure – through the incorporation of formal hysterectomy guidelines (a surgical decision tree algorithm) and standardised VH technique into the resident training programme.

Materials and methods

The study was approved by the Ethics Committee of the University of Witwatersrand (ref. Nr: M150462) and realized at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). CMJAH is a tertiary-level academic hospital and a referral centre for the eastern and western areas of greater Johannesburg. The Department of Obstetrics and Gynaecology is associated with the University of the Witwatersrand, and is thus a provider of training to undergraduate and postgraduate students. Guidelines (Fig. 1) were introduced as part of academic programme to improve teaching among the residents.

All patients admitted between July 2001 and December 2014 (the period covered by the study) due to benign conditions, meeting the inclusion criteria (*i.e.* vaginally accessible uterus, uterine size equivalent to ≤12 weeks of gestation or ≤280 g on ultrasound examination, pathology confined to the uterus; Fig. 1) were included. According to the guidelines set by the Unit, nulliparous women, women without uterine descent, women with previous pelvic surgery or caesarean section, women requiring salpingo-oophorectomy, and women with persistent cervical dysplasia after previous large loop excision of the transformation zone (LLETZ) or endometrial hyperplasia without atypia on endometrial sample were also included.

Women with utero-vaginal prolapse who underwent VH were also included in the study but analysed separately. The surgical route was determined using the study surgical decision tree algorithm (Fig. 1). In cases where the pathology was suspected not to be confined to the uterus or success of the vaginal route was uncertain, LAVH was performed.

All the VH procedures were performed by the residents in training, under the supervision of the head of the Unit (A.C.) or specialists within the Unit with thorough experience in vaginal surgery. During the study period, a standardised surgical technique [30] was used, for both VH and LAVH. A brief description of the VH and LAVH used in the study is shown in Panel 1. All patients received prophylactic antibiotics intra-operatively.

The patient characteristics at inclusion, the indications for hysterectomy, the weights of the uteri, the length of hospital stay, and intra-operative and immediate post-operative complications, among those who underwent VH and LAVH were recorded and analysed. The operative time was calculated as the time that elapsed from the first cut to the closure of the abdominal incisions in cases of LAVH, or of the vaginal vault in cases of VH. Descriptive statistics were engaged for socio-demographic characterisation of the study population. All continuous data were compared using the Student *t*-test. The Chi-square test and Kruskal-Wallis test were used to compare the difference between LAVH and VH groups. Pearson's correlation coefficient was calculated to assess the relationship between the clinic and/ or demographic factors of the patients. The results were considered to be statistically significant if a p-value <0.05 was obtained (CI 95 %).

Results

A total of 3925 women underwent hysterectomy during the study period in our department: 2782 (70,8%) had AH, 1017 (26 %) VH, and 126 (3,2%) LAVH. A year before the beginning of the study, the percentage of VH in our Institution was 9.8 % of all hysterectomies. The procedure was mainly performed for utero-vaginal prolapse. Introducing formal guidelines, a surgical decision tree algorithm, and a standardised surgical technique resulted in an increase in the rate of VH to 48.4 %, and an overall decline in open AH from 91.2%–51,6% (Fig. 2). Thus, VH to AH ratio increased from 1:9 at the beginning of the study (July 2001) to 1:1 by its end (December 2014). A sharp increase in LAVH was observed from July 2001 to December 2004, reaching a maximum of 10.8 %, and dropping to 1,25 % by the end of the period studied (December 2014). As experience was gained with VH, the total number of VH increased with a decrease in the need for LAVH (Fig. 2).

After following the surgical decision tree algorithm, 1017 VHs and 126 LAVHs were performed in the department during the study period. Thus, a total of 1143 patients submitted to minimally invasive procedures (VH or LAVH) were included in the study. The cases who underwent AH (2782 patients) mainly included women with cervical and endometrial malignancies, and patients with abnormal uterine bleeding not responding to medical treatment and the uterine size exceeding 12 weeks of gestation on clinical

Panel 1
VH and LAVH techniques used in the study.

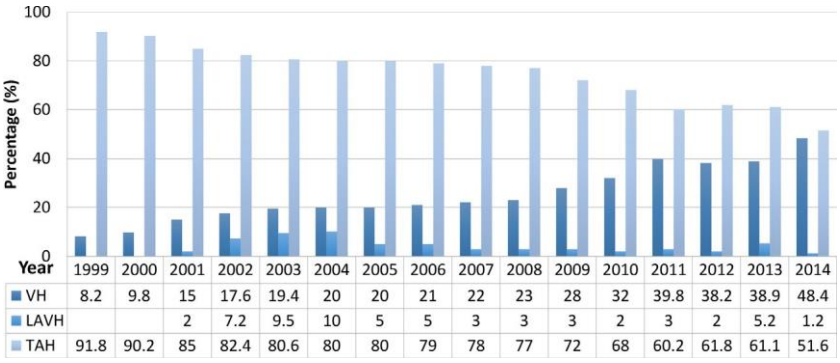
VH:

1. General or regional (spinal) anaesthesia
2. Patient placement in dorsal lithotomy position with her feet in stirrups
3. Exposure of the cervix, circular incision around the cervico-vaginal junction
4. Opening of the anterior and posterior peritoneum, preferentially before the clamping, cutting and ligating of the utero-sacral and cardinal ligaments
5. Clamping, cutting and ligating of the uterine vessel pedicle, containing the uterine artery and vein, and the broad ligament peritoneum anterior and posterior to these vessels, with a 0 or 2.0 delayed absorbable suture
6. Clamping, cutting and ligating of the remaining portion of the broad ligament attached to the uterus (containing the round and ovarian ligaments, the proximal part of the fallopian tube and blood vessels) with 0 or 2.0 delayed absorbable suture
7. Closing the peritoneum and the vaginal
8. Insertion of the urine catheter and vaginal plug

LAVH:

1. Laparoscopic assessment of the pelvic organs, release of adhesions, treatment of endometriosis where necessary, and freeing the adnexa
2. VH as described above, with laparoscope left *in situ* to assess the progress and any complication of the procedure
3. Laparoscopic assessment of haemostasis and removal of the blood clots and debris

Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; VH, vaginal hysterectomy.



Year	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
VH	8.2	9.8	15	17.6	19.4	20	20	21	22	23	28	32	39.8	38.2	38.9	48.4
LAVH			2	7.2	9.5	10	5	5	3	3	3	2	3	2	5.2	1.2
TAH	91.8	90.2	85	82.4	80.6	80	80	79	78	77	72	68	60.2	61.8	61.1	51.6

Fig. 2. Vaginal hysterectomy (VH), laparoscopically-assisted vaginal hysterectomy (LAVH) and total abdominal hysterectomy (TAH) presented as a percentage of all hysterectomies performed at the Department of Obstetrics and Gynaecology of the Charlotte Maxeke Johannesburg Academic Hospital during the period July 1999 – December 2014.

Table 1
Patient characteristics.

Hysterectomy approach (number of the patients)	VH (n = 1017)	LAVH (n = 126)
Mean age (SD), years	50.1 (11.9)	43.9 (9.3) *
Parity (SD), number of children	2.7 (1.3)	1,9 (1.0) *
Median uterus weight measured after the surgery (range), g	70.0(20 380)	100.4 (25 420) *

* VH *vs.* LAVH group p-value<0.0001; Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; SD, standard deviation; VH, vaginal hysterectomy.

Table 2
Indications for hysterectomy.

Indication	VH group, n(%)	LAVH group, n(%)	p-value
Cervical dysplasia	541 (53.1)	49 (38.8)	0.0026
Multifibroid uterus	397 (39.0)	43 (34.1)	0.29
Heavy menstrual bleeding	30 (2.9)	16 (12.6)	<0.0001
Post-menopausal bleeding	18 (1.8)	2 (1.5)	1.00
Adenomyosis	17 (1,7)	6 (4.8)	0.033
Dysfunctional uterine bleeding	9 (0.9)	1 (0.8)	1.00
Endometrial polyp, hyperplasia	8 (0.8)	1 (0.8)	1.00
Chronic pelvic pain	6 (0.6)	1 (0.8)	0.56

Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; VH, vaginal hysterectomy.Note: Patients could have more than one indication each.

Table 3
Comparison of operation time (not including anaesthetic time) post-operative course between VH for prolapse, VH for non-prolapse indications and LAVH.

Hysterectomy approach	VH (n = 1017)	VH prolapse (n = 123)	VH non-prolapse (n = 894)	LAVH (n = 126)
Median operation time (IQR), minutes	30.1 (20 90)	29.4 (20 50)	30.9 (20 45)	67.2 (50 90) *
Median hospital stay (IQR), days	2.1 (2 4)	2.1 (2 4)	2.1 (2 4)	2.1 (2 4)
Median number of opiate injections required (IQR)	3.0 (2 4)	3.0 (2 4)	3.0 (2 4)	3.0 (2 4)

* p-value < 0.001 when compared with LAVH group; Abbreviations: IQR, interquartile range; LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; VH, vaginal hysterectomy.

evaluation or 280 g on ultrasound examination. The patient characteristics, including the uterine weight, for all the VHs and LAVHs are presented in Table 1. The most common indications were cervical dysplasia, uterine fibroids and heavy menstrual bleeding, followed by post-menopausal bleeding, adenomyosis, dysfunctional uterine bleeding, endometrial hyperplasia and chronic pelvic pain (Table 2). In all cases, the procedure was successfully performed in terms that there was no need for conversion to open abdominal hysterectomy. The mean time required for LAVH was 67.2 min, significantly longer compared to VH for prolapse, 29,4 min, or VH for non-prolapse indication, 30,9 min as well ($p < 0.001$; Table 3). The postoperative hospital stay and the convalescence time were similar for VH (prolapsed uterus), VH (non-prolapsed uterus) and LAVH procedures – 2.1 days (range 2 4 days), respectively. There was no statistically significant difference regarding the postoperative pain and the need of analgesia between the patients submitted to VH and those from the LAVH group (Table3).

Vaginal hysterectomy for utero-vaginal prolapse was performed in 123 (10,7%) of the 1143 patients. The patients with prolapse were older than their non-prolapsed counterparts, had an increased parity and had significantly lower uterine weights with a median of 42,5 g (range 20 103) compared to 90,4 g (range 20 380) for those without prolapse and 100,4 g for those who underwent LAVH (25 420), $p < 0.001$ (Table 4). When patients with non-prolapsed uterus submitted to VH were compared with the women who underwent LAVH, there was no significant difference in uterine weight (Table 4).

Intra-operative and immediate post-operative complications are presented in Table 5. Five bladder perforations (0.43 %)

Table 4
Patient characteristics between VH for prolapse, VH for non-prolapse and LAVH groups.

Hysterectomy approach	VH prolapse (n = 123)	VH non-prolapse (n = 894)	LAVH (n = 126)
Mean age (SD), years	63.1 (9.4)	49.2 (11.2)	43.9 (9.3)*
Median parity (range), number of children	4 (1 7)	2 (0 5)	2 (0 4)*
Median uterus weightmeasured after the operation (range), g	42.5 (20 103)	90.4 (20 380)	100.4 (25 420)*

* p-value < 0.001 when compared with VH prolapse group; Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; SD, standard deviation; VH, vaginal hysterectomy.

Table 5
Complications occurring intra-operatively and in the immediate postoperative period in VH and LAVH group.

Complications		VH (n = 1017)	LAVH (n = 126)	p-value
Major	Urinary tract damage			
	Bladder injury	3 (0.3 %)	2 (1.6 %)	0.10
	Ureteric injury	0	0	
	Haemorrhage necessitating blood transfusion and relook laparotomy	4 (0.4 %)	1 (0.8 %)	0.44
	Bowel damage	0	0	—
	Deep vein thrombosis	0	0	—
	Minor	Pyrexia requiring antibiotics	0	0
		Wound sepsis	0	0
Wound dehiscence		0	0	—
Conversion to open abdominal hysterectomy		0	0	—

Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; VH, vaginal hysterectomy.

occurred during the study period, 3 in the VH group and 2 in LAVH group. Five patients (0.43 %) had a relook laparotomy due to a bleeding in the immediate post-operative period, 4 in VH and 1 in LAVH group respectively. There were not bowel injuries or other complications (Table 5).

Discussion

This study demonstrates that the use of formal guidelines, a clinical decision tree algorithm, and a standardised surgical technique, as well as the incorporation of these guidelines into the residents training programme, can increase the rate of VH and result in an overall decline in open AH and LAVH. This study is in agreement with other large studies, which indicate that, the implementation of a clinical pathway and hysterectomy guidelines can be associated with a decrease in the proportion of hysterectomies performed abdominally [31–34]. In our Institution, the proportion of hysterectomies performed abdominally decreased from 91.2%–51.6% and those performed vaginally increased from 9.8%–48.4% from the beginning of the study in July 2001 its end in December 2014 (Fig. 2). The VH to AH ratio, therefore, was increased from 1:9 to 1:1. Based on this, it seems that as much as 40 % of feasible vaginal procedures were replaced by a more invasive approach, AH, when the surgical decision algorithm was not used.

Between 2014 and 2019 the rate of VH has been sustained and remains the same (unpublished data). We agree with Moen et al. that, improving the use of VH among our residents can only be achieved by addressing the key issues of training and maintaining skills in the technique and by increasing awareness of the scientific evidence supporting its use [15].

AH rates worldwide remain very high [28], despite well-documented evidence that VH has distinct benefits over other routes [3–7,31–36]. However, some surgeons remain reluctant to change their practice patterns, and continue to select the abdominal route for most operations without documenting that the vaginal route is contraindicated The surgical decision tree algorithm in Fig. 1 offers gynaecologic surgeons a structured approach for selecting the appropriate surgical technique.

Another reason for the extremely high rates of AH seen today is that well-established evidence-based guidelines for hysterectomy are ignored by practising gynaecologists [21,31–34] which results in the abdominal route being chosen based on the surgeon's personal preference, in many circumstances without patient being informed about the VH option [37]. This arbitrary approach is not justifiable: there are significant differences in the medical outcome of VH as compared with TAH and LH [3,6–8,46,49]. The American Association of Gynaecologic Laparoscopists (AAGL) recommends that surgeons without the requisite training and skills required for the safe performance of VH or LH should enlist the aid of colleagues who do, or should refer patients requiring hysterectomy to such individuals for their surgical care [38].

As presented in Fig. 1, if there is suspicion of pathology outside of the uterus, or the physician is not sure about the likely success of VH, LAVH can and should be performed. The laparoscopic component of VH aims to restore pelvic anatomy and free the adnexa. Nothing is gained by continuing the dissection laparoscopically, since not only does this considerably and unnecessarily prolong the surgery but it may also increase the risk of visceral damage and haemorrhage [48,49].

An interesting observation during the study period was that as VH increased, the need of LAVH decreased. With initially increasing use of LAVH the surgeon becomes more confident in the pre-operative assessment of operability by a history, bimanual examination and pelvic sonar and more confident to operate "blind" (VH), discovering that the laparoscopic component is most often superfluous. When focus is directed towards VH, the need for laparoscopic assistance decreases as experienced with VH is gained (Fig. 2). This finding is opposed to other studies, which have shown that if the focus is directed to LH, there is a resulting significant reduction in rates of VH to below 10 %, without perceptible impact on AH rates [21,39,40]. The advent of robotic hysterectomy (RH) may also contribute to declines in VH rates [41].

Our results are also in agreement with other studies, which demonstrated that VH required significantly shorter operating time compare to LH [3–8]. The postoperative hospital stay and the convalescence time were identical for LAVH and VH. The

postoperative pain and the need of analgesia did not differ between the two groups (Table 3).

Our results of 0.3 % and 1.6 % bladder injuries during VH and LAVH, respectively, are comparable to previously reported incidences of 0.6–2.5% [35,42–44]. There were no injuries to the bowel recorded. Conversion to laparotomy has been found by others to be higher during LH as opposed to VH [45,46]. The absence of conversion in our series may be due to the fact that all the cases were performed in one centre under the supervision of experienced vaginal surgeons in which a residency programme actively sought to teach VH.

In the immediate postoperative period, our 5 patients required a relook laparotomy for bleeding. These five patients (0.4 %) received blood transfusions, 4 in VH and 1 in LAVH groups respectively (Table 5) which is much less compared to other large studies, which reported postoperative haemorrhage of 0,9 – 2,5% [33,42,43,46].

In a survey performed among South African practising gynaecologists about preferred and implemented methods of hysterectomy, 46 % of the responders indicated lack of training and experience as the main reason of not performing VH [47]. Less emphasis on vaginal surgery in resident training programmes, the absence of clear guidelines for selecting appropriate candidates for VH as shown in Fig. 1, and the lack of patient knowledge about surgical options results in the low rates of VH seen today. Several studies have shown that VH can be successfully performed in 90–100% patients with benign disease by use of a formal decision-making process to determine the correct route [31–34,48,49].

Regarding training of VH during residency, it is important to distinguish between proficiency and exposure. In a survey about resident opinions on VH training performed in United States of America, 75 % of the responders indicated that, in order to achieve proficiency during residency, more than 20 cases of VH are necessary [50]. The American College of Obstetrics and Gynaecology (ACOG) requests the number of 15 cases to be performed before completing the residency programme. In Nigeria, VH is underutilised as most centres hardly conduct more than five VHs in a year [51]. The situation in South Africa is similarly problematic because the South African College of Medicine (CMSA) requires only five VHs to be performed during a residency programme of four years. With these numbers, exposure is achieved but not proficiency. The future gynaecologist, not proficient to perform VH, may be inclined to perform hysterectomy by the abdominal route when it could be safely performed vaginally. This lack of proficiency also increases the likelihood of litigation should complications arise.

The programme introduced by our unit has been tested extensively, as more than 1000 hysterectomies have been safely performed vaginally during the period studied. By increasing the rate of VH in our institution, we achieved greater exposure and training at resident level, providing the possibility of true proficiency that could be passed to others.

Conclusion

This study provides proof of the concept that introducing formal institutional guidelines and using a standardised surgical technique can significantly increase the number of VHs in patients with benign gynaecological conditions and without uterine prolapse. In addition to the benefits that patients have, this strategy enables an increasing number of residents to perform VH and obtain the necessary proficiency.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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A randomized control trial comparing vaginal and laparoscopically- assisted vaginal hysterectomy in the absence of uterine prolapse in aSouth African tertiary institution

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abstract

Objectives: The primary objectives of this study were to estimate blood loss, operation time and cost dif- ferences in patients undergoing vaginal hysterectomy (VH) *versus* laparoscopically-assisted vaginal hys- terectomy (LAVH). The secondary objectives were to determine differences in hospital stay, need for postoperative analgesia, intra- and immediate post-operative complications, and the rate of conversion to laparotomy. VH was hypothesized to be the preferred route for hysterectomy for benign uterine con- ditions.

Study Design: A randomized control study was undertaken at the Department of Obstetrics and Gynaecology of the Charlotte Maxeke Johannesburg Academic Hospital and included the women admit- ted between January 2017 and December 2019 for hysterectomy due to benign conditions, meeting the inclusion criteria (vaginally accessible uterus, estimated uterine size ::: 12 weeks of gestation or ::: 280 g on ultrasound examination and pathology confined to the uterus). Surgical procedures were performed by the residents in training under the supervision of specialists with large experience. The patient demo- graphic characteristics, uterine weight, operative time, estimated blood loss (expressed as the difference between preoperative and postoperative day one serum haemoglobin), direct surgery-associated costs, intra- and immediate post-operative complications and the length of hospital stay were recorded and comparatively analysed among patients randomly placed in VH and LAVH group.

Results: A total of 227 women were included (151 patients underwent VH and 76 LAVH, upon 2:1 ran- domization, performed on this way to reflect the previous pattern of operating of the unit). The patients were matched with respect to age, parity and body mass index. No significant differences between two groups were found in mean uterine weight and also in mean serum haemoglobin shift, intra- and imme- diate post-operative complications, and convalescence period duration. There were statistically signif- icant differences in operating time and in cost between the two procedures. On average, LAVH took longer than VH to be performed (62.8 ± 9.3 *vs* 29.9 ± 6.6 min, p <0.0001) and it was more costly, mainly due to the longer operating time and required disposables. An amount of 15698.20 South African Rand (ZAR) or 1145.85 United States Dollar (USD) more were needed to perform LAVH in comparison to VH. All VHs and LAVHs were successfully accomplished without major complications or conversation to laparotomy.

Conclusion: Our data indicate that VH is a feasible and safe alternative for a large group of women with benign pathology and non-prolapsed uteri, being a faster and less costly procedure than LAVH.

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Introduction

Hysterectomy remains one of the most common operative pro- cedures for benign gynaecological diseases [1,2]. Even though vagi- nal hysterectomy (VH) or laparoscopic hysterectomy (LH) should be the preferred, based on their well-documented benefits [3–7], the practice of abdominal hysterectomy (AH) predominates [8,9]. It can be explained, in part, by personal choice, but a lack of train-ing and experience may also result in the surgeon's reluctance to perform VH. This is the case particularly in the non-prolapsed uterus, in nulliparous woman, in the presence of uterine enlarge- ment, in women with previous gynaecological surgery or in women who have undergone a previous caesarean section. The above factors should not be considered as contraindications to per- form VH [9–11]. Since the introduction of LH by Reich in 1989 [12], the mode of hysterectomy became an issue of debate especially in cases of non-prolapsed uterus. Laparoscopically-assisted VH (LAVH) has a place if the surgeon is uncertain about the success of VH or if extra-uterine pathology is suspected. There are few tri- als comparing the outcomes of LAVH *versus* VH [3–7,13–18]. This study compares VH and LAVH in terms of operative time, blood loss, other intraoperative and immediate postoperative complica- tions, average length of hospital stay and costs.

Material and methods

This single-blinded randomized control trial was performed between January 2017 and December 2019 at the Urogynaecology and Endoscopy Unit of the Charlotte Maxeke Johannesburg Aca- demic Hospital (CMJAH), which is a tertiary level referral hospital for the greater Eastern and Western Johannesburg region. Women admitted for hysterectomy for benign uterine conditions meeting the inclusion criteria set by the Unit (*i.e.,* vaginally accessible uterus, uterine size equivalent to 12 weeks of gestation or 280 g on ultrasound examination and pathology confined to the uterus) were included in the study (Fig. 1). Patients with uter- ine prolapse were excluded. Women were randomly allocated into two intervention groups (the VH and LAVH group, Fig. 1). The ran- domization procedure was systematic and based on a generated list that makes use of serially numbered, opaque envelopes. Each patient was allocated a study number and the corresponding envelope was issued to them by a blinded physician. The envelope was opened in the ward the day before surgery. The patient was counselled and consent for the designated procedure was given.

Sample size calculation

Sample size calculation was based on the primary objective, to compare operative time and blood loss (determined by a decrease in serum haemoglobin) for VH and LAVH, based on mean pre-to- post-operative haemoglobin difference of 1.41 +/- 1 g/dL in VH and 1.8 +/- 1 g/dL in LAVH with an 80 % power. Stata 14.1 statistical software was used to determine the minimum sample size required to find significant difference for Satterthwaite's *t* test assuming unequal variances between the VH and LAVH, with a ratio of 2:1, used to more normally reflect the previous pattern of operating of the unit.

Surgical techniques used in the study

All the procedures were performed by the residents in training, under the supervision of the study primary investigator (AC) or other specialist with large experience. Standardized surgical tech- niques [19] were used, for both VH and LAVH (Fig. 3). All patients received prophylactic antibiotic intra-operatively.

Variables

The patient age, parity, body mass index, indication for hys- terectomy and ultrasound-determined weight of the uterus were recorded at inclusion. Outcome variables amongst those who underwent VH and LAVH were recorded and analysed, including length of post-operative hospital stay, intra-operative and immedi- ate post-operative complications (bladder perforations, conversion to AH and need for second-look laparotomies), and post-operative pain (need for analgesia). The operative time was measured for each procedure, calculated as the time that elapsed from the first cut to the closure of the abdominal incisions in cases of LAVH or to the closure of the vaginal vault in cases of VH. The costing was done from the provider's perspective (the hospital) and focussed on direct costs. Indirect costs included costs for labora- tory investigations, medications not related to the procedure, drugs used after the operation for either analgesia or pain control and management of complications if any. These indirect costs or "ward charges" were not included in the costing. Only variable direct costs were included, since fixed direct costs (*e.g.* capital costs, overheads) were assumed constant regardless of the type of procedure. The direct costs included charges for operating time per minute and consumables used for the procedures, LAVH and VH only. The medical aid scheme rate corroborated with the pri- vate sector was used to determine the cost of operation time per minute. The price of disposable instruments used for the proce- dures was obtained from three different companies (Johnson & Johnson Medical SA, Covidien-Medtronic SA and LigaSure™), which supplied the hospital during the study period. Professional fees, which included the amount paid to the surgeon, the assistant, the anaesthetist, and the theatre staff during the procedure, were not included in the analysis, as this is a state-run facility with sal- aried employees. The hospital charges for VH and LAVH performed during the study period which include ward fees, from admission to discharge, were not included in the analysis as there was not a significant difference in hospital stay and analgesia needed between the two procedures. The direct cost of the VH and LAVH procedures, which included operation time and consumables, are shown in ZAR and USD, based on the mean exchange rates during the study period, which was 1 USD = 13,7 ZAR (January 2017: 1 USD = 13,4 ZAR; December 2019: 1 USD = 14,0 ZAR).

Statistical analysis

Data were analysed with STATA v 14.1. Mean and standard deviation, median and IQR, and proportions were used to describe the socio-demographic characteristics and outcomes of the study participants. Continuous data, if normally distributed, were com- pared between LAVH and VH groups using the student *t*-test, otherwise a Mann-Whitney test was applied. For categorical data a Chi-square test was used to compare categorical variables between LAVH and VH groups. The results were considered to be statistically significant for a p-value < 0.05.

Results

Seven hundred and twenty-three women underwent hysterec- tomy during the study period in our institution: 381 (51,7%) had AH while 342 (49,2%) underwent VH [286 (39,7%) VH and 76 (95%) LAVH] (Figs. 1 and 2). According to the study protocol, a total of 227 patients were included in the trial (Fig. 1). Hundred and fifty-one patients underwent VH and 76 underwent LAVH. The patient demographic characteristics at inclusion, as well as the weights of the uteri among those who underwent VH and LAVH are presented in Table 1. The mean age of the patients who under-

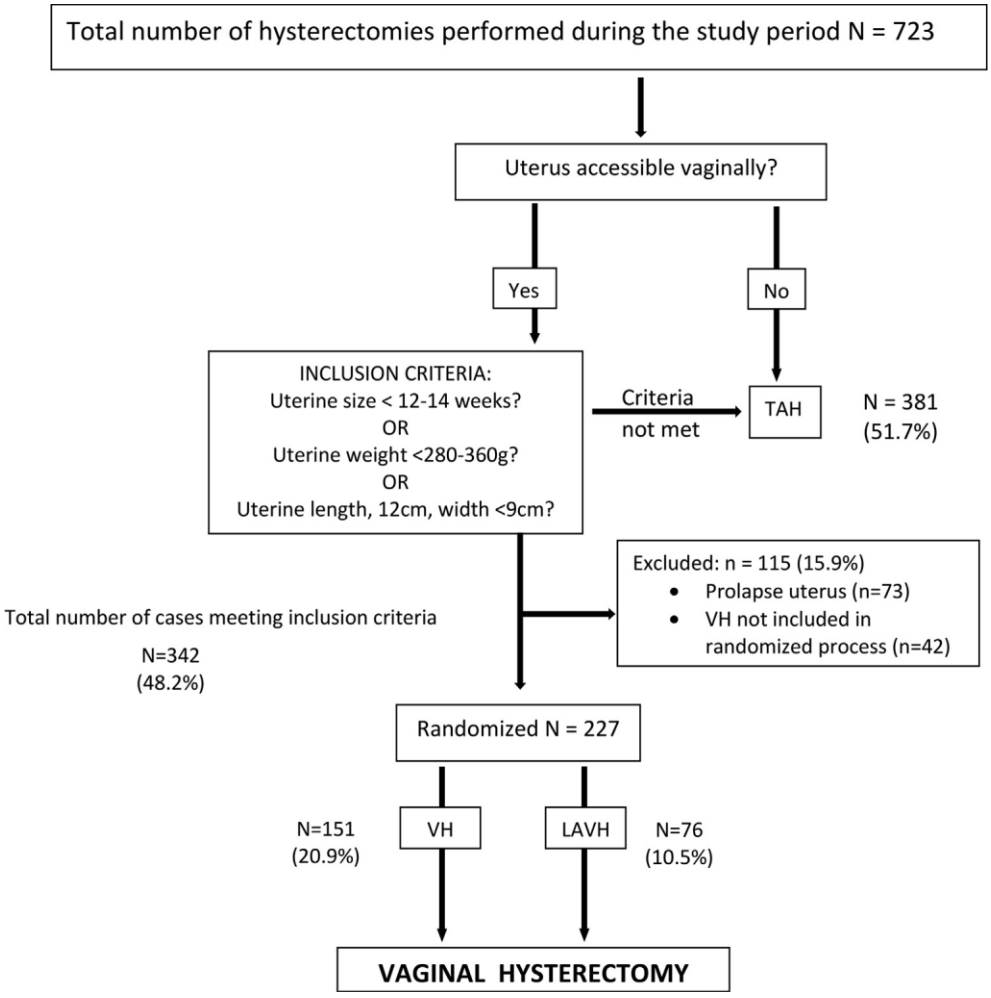

Fig. 1. Enrolment of the patients and their allocation to hysterectomy groups.

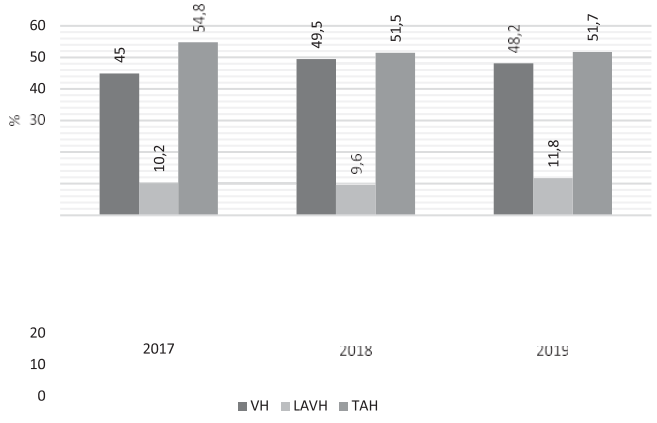

Fig. 2. Percentages of hysterectomies performed per year over the study period.

The most common indications for VH and LAVH were cervical dysplasia, uterine fibroids, excessive menstrual bleeding, followed by post-menopausal bleeding and adenomyosis (Table 2). The time required for LAVH was significantly longer as compared to VH(62.8 ± 9.3 ***VS*** 29.9 ± 6.6 min, $p < 0.01$). The average postoperative hospital length of stay and the convalescence time were similar for

went VH and LAVH was 47.1 ± 9.9 and 45.6 ± 8.0,respectively ($p = 0.22$). The mean uterine weight of the patients who underwent VH and LAVH was 91,58 (range 20 – 644 g) and 88, 4 (range 25 – 234g), respectively ($p = 0.26$).No statistically significant difference in parity, body mass index (BMI) and uterine weight was observed amongst the two procedures, VH and LAVH (Table 1).

both procedures, 2.2 days for LAVH (IQR 2–4 days) and 2.2 days for VH (IQR 2–4). Postoperative pain and the need of analgesia (pethi- dine administration) were similar for both the VH and LAVH groups (Table3). As shown in Table 3, there were no statistically significant differences in blood loss between VH and LAVH as determined by a median decrease in serum haemoglobin (Hb) levels in a day one post-hysterectomy.

The mean time of the LAVH in our study took 32.9 min longer than VH. The total cost of extra theatre time needed to perform LAVH as compared to VH was estimated to be 6366,15 ZAR or 464,68 USD. The resources used during the surgery contributing to the variable direct costs and the estimative of the variable direct cost per hysterectomy procedure (VH *VS* LAVH) are presented in Table 4.The cost of suture materials used during the two proce- dures were similar. The mean cost of consumables per LAVH, reg- ularly used by the Unit, as shown in Table 4, was estimated to be 9332.05 ZAR or 681,17 USD. Considering the extra theatre time and the consumables used during LAVH, an amount of 15698.20 ZAR or 1145,85 USD more was needed to perform LAVH as opposed to VH.

Regarding the intra-operative and immediate post-operative complications, three bladder perforations (1,3%) occurred – 2 dur- ing VH (1,3%) and 1 during LAVH (1,3%). No intra-operative conver- sion to open AH occurred for either VH or LAVH and no patient had a "second- look" laparotomy or laparoscopy due to bleeding or other reasons in the immediate post-operative period.

Vaginal hysterectomy (VH):

After appropriate general or regional (spinal) anaesthesia administration, the patient was placed in dorsal lithotomy position with her feet in stirrups.

2. The cervix was exposed and a circular incision around the cervico-vaginal junction was performed.
3. The anterior and posterior peritoneum was preferentially opened before the clamping and the cutting of the utero-sacral and cardinal ligaments.
4. Both uterine vessel pedicle, containing the uterine artery and vein, and the broad ligament peritoneum anterior and posterior to these vessels, were clamped, cut, and ligated with a 0 or 2.0 delayed absorbable suture. In cases of enlarged multifibroid uteri, the morcellation method used in this study was by means of vaginal myomectomy after securing the uterine vessels.
5. The remaining portion of the broad ligament attached to the uterus (containing the round and ovarian ligaments, the proximal part of the fallopian tube and blood vessels) was then clamped, cut, and ligated with 0 or 2.0 delayed absorbable suture.
6. Once VH were performed, the peritoneum and the vaginal vault were closed. Urine catheter and vaginal plug were inserted and removed the following day.

Laparoscopically-assisted vaginal hysterectomy (LAVH):

The laparoscopic component of the LAVH includes the assessment of the pelvic organs, release of adhesions, treatment of endometriosis where necessary, and freeing the adnexa.

2. The rest of the operation was then undertaken vaginally. The laparoscope was left *in situ* to assess the progress and any complication of the procedure.
3. Following VH and the closure of the vaginal vault, laparoscopy was performed to assess haemostasis and to flush out blood clots and debris.

Fig. 3. Surgical techniques used in the study.

Table 1

Patient demographic characteristics and uterine weight (VH vs LAVH group).

Hysterectomy approach (number of patients)	VH (n = 151)	LAVH (n = 76)	p-value
Age, years [mean (SD)]	47.1 (9.9)	45.5 (8.0)	0.22
Parity [median (IQR)]	2 (0–6)	2 (1.5–3)	0.05
Body mass index, kg/m^2 [mean (SD)]	29.1 (6.8)	27.4 (6.3)	0.03
Uterus weight,g [Mean (SD)]	91,5 (90,1)	88,4 (50.2)	0.26

Abbreviations: IQR, interquartile range; g, gram; Kg, kilogram; LAVH, laparoscopic-assisted vaginal hysterectomy; m^2, square meter; n, number; SD, standard devia- tion; VH, vaginal hysterectomy.

Table 2

Indications for hysterectomy.

Indication	VH group Number (%)	LAVH group Number (%)	p-value
Cervical dysplasia	86(57.3)	46 (61.3)	0.61
Multifibroid uterus	82 (54.6)	42 (56.0)	0.89
Heavy menstrual bleeding	19 (12,6)	16 (21.3)	0.10
Adenomyosis	9 (6.0)	6 (8.0)	0.77
Post-menopausal bleeding	4 (2.6)	2 (2.7)	1.00

Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; n, number; VH, vaginal hysterectomy. Note: Patients could have more than one indication each.

Discussion

VH is a feasible and safe option for patients with benign pathol- ogy and non-prolapsed uterus. In our study, there were no signifi- cant differences in blood loss between VH and LAVH. No patient necessitated blood transfusion, either those submitted to VH or LAVH. Some previous studies showed that a significantly higher blood loss was observed during VH as compared to LAVH [14–16]. Reduced drop in haemoglobin levels of VH, as compared to LAVH and total laparoscopic hysterectomy (TLH), was found by McCracken *et al.* [17]. This study is in support of recent systematic review and *meta*-analysis indicating that there are no significant differences in blood loss between VH and LH, either TLH or LAVH [18,19].

Regarding the cost implications of performing VH as opposed to LAVH, four randomized control trials (RCTs) found that VH was less costly, primarily due to operating time and the use of disposable instruments during LAVH [4,20–23]. Kovac *et al.* found that by using guidelines to assist clinical decision-making for hysterec-

Table 3

Comparison of operation time, blood loss and postoperative course between VH and LAVH.

Hysterectomy approach	VH	LAVH	p-value
Operation time*, minutes [mean (SD)]	29.9 (6.6)	62.8 (9.3)	<0.01
Hospital stay, days [median (IQR)]	2 (2–2)	2 (2–3)	0.06
Opiate injections required [n (%)]			< 0.01
2 injections	18 (12)	0 (0)	
3 injections	73 (48)	39 (51)	
4 injections	60 (40)	37(49)	
Pre-operative Hb, g/dL [median (IQR)]	13.2 (12.2–13.6)	13.0 (11.9–13.9)	0.42
Postoperative Hb, g/dL [median (IQR)]	11.3 (10.6–12.2)	11.2 (10.0–12.1)	0.76
Difference between pre- and postoperative Hb, g/dL [median (IQR)]	1.5 (1–2.2)	1.40 (0.95–2.35)	0.89

*Anaesthetic time not included.

Abbreviations: dL, deciliter; IQR, interquartile range; g, gram; Hb, hemoglobin; LAVH, laparoscopic-assisted vaginal hysterectomy; VH, vaginal hysterectomy.

Table 4

Estimated variable direct cost per LAVH *vs* VH.

Resource items	Estimated cost per procedure (ZAR)	
	LAVH	VH
Surgical cost per mean operating time	12151.80	5785.65
Sutures used	258.10	260.55
Other consumables used	9332.50*	0.00
Total	21742.40	6046.20

*Consumables used during LAVH (LigaSure™ bipolar vessel sealing device was used for all the LAVHs, whereas for trocars, sleeves and graspers the mean price of three different suppliers was used into the cost calculation).

Abbreviations: LAVH, laparoscopic-assisted vaginal hysterectomy; VH, vaginal hysterectomy; ZAR, South Africa rand.

tomy, a potential savings of 1.2 million (US) could be attained for every 1.000 hysterectomies performed vaginally [23]. Our results are in agreement with these studies demonstrating that the average hospital charges are significantly higher in LAVH as compared to VH [4,20–23]. The main sources of the cost difference between LAVH and VH were related to the differences in operation time and the cost of consumables used during LAVH compared to VH which requires no additional specific materials. The cost of operation time per minute in our study was 193,50 ZAR or 14,1 USD, excluding consumables used, and did not include the surgical team and theatre support staff to perform the procedures. One minute of operating time cost vary from country to country and sometimes from state to state. Accordingly to Childers *et al.* (2018), the mean cost of operating time was 36 to 37 USD per minute, if the procedure was performed in California in the United States of America (USA) [24]. A 2005 study including 100 USA hospitals found that operation time charges averaged 62 USD per minute (range: 22 to 133 USD per minute). The operating room expenses are expected to increase more rapidly than the consumer price index [24]. Reducing the operation time by increasing the number of VH as opposed to open AH or LH, would have an positive impact on cost reduction programs especially for the low resources countries like South Africa.

We estimate that by opting to perform VH instead of LAVH, as much as 15,6 million ZAR or 1,14 million USD could be saved for every 1.000 hysterectomies performed vaginally in South Africa. When cost analysis was undertaken for this study, VH found to be much cheaper than LAVH. With more than 500.000 hysterectomies performed annually in the United States, and more than 100.000 in the United Kingdom, the vaginal approach seems even more relevant in this time of economic strain [22].

It would also be interesting to quantify and compare the costs of learning surgical techniques. However, this was not possible in our clinical settings where academic programs are at least partially free of charge while employees are paid without additional fees for teaching a particular surgical technique.

The results of this study are in support of other RCTs which showed the same benefits of short hospital stay, rapid recovery and need of analgesia between VH and LAVH [3,6,7]. When focused on the operation time, LAVH took 32,9 min longer than VH to be performed for patient with similar indication and uterine weight ($p < 0.001$). Our study thus confirms that VH requires significantly shorter operating time compare to LH [3–8,14–18,30]. This is also in agreement with the findings of the 2009 Cochrane review which concluded that LAVH takes 39.3 min longer than VH [3]. Extra time taken with LAVH does affect what can be achieved on any individual operating list. No significant differences in complication rates were found in this study between LAVH and VH. Other studies found fewer complications with VH, when comparing this to all other hysterectomy routes [3,6,7,32,34]. A RCT conducted by Richardson *et al.* clearly concluded that if LH is done, it should be converted to a vaginal procedure as early as possible to reduce the overall complications and operating time [33]. More frequent complications of LH or TLH as compared to VH include bladder, ureter and bowel injuries [32–37]. The absence of conversion to laparotomy in our series may be due to the fact that all the cases were performed in one centre under the supervision of experienced vaginal surgeons in which a residency programme actively sought to teach VH. During the study period, the learning curve was found to be short as the residents were guided through the VH steps by an expert assisting team. It can be reasonably considered that such expert guidance through practical training did condition the good results of this study. Teacher experience, teaching quality, learning curve, and successful outcomes in surgery are positively interrelated variables.

The postoperative hospital stay and the convalescence time were identical for LAVH and VH (2.2 days). The postoperative pain and the need of analgesia were the same for both groups of our study. Conversion to laparotomy rate was found by others to be higher during LH as opposed to VH [32,33,34,37].

The use of specific guidelines to select the route of hysterectomy has been proposed [25–27]. In 2020, the International Society for Gynecologic Endoscopy (ISGE) published evidence based practical guidelines to promote the safe performance of VH for non-prolapsed uterus [13]. This study showed that if formal guidelines are in place and standardized surgical technique of performing VH is in use, all the hysterectomies for non-prolapse uterus meeting the inclusion criteria can be performed by the vaginal route successfully without major complications or conversation to laparotomy. As demonstrated previously by others [28–30], LAVH has its place when there is uncertainty of a successful VH, or in order to perform adhesiolysis, treat endometriosis and restore pelvic anatomy. All the LAVHs were successfully performed during this study and no complications encountered. Despite evidence supporting the benefit of VH, current statistics indicated that VH is underutilised [11]. The decrease in utilisation of VH are considered

to result from the lack of training and experience in resident train- ing programs [31]. The shift in training from VH to laparoscopi capproaches at resident level, the fascination of new laparoscopic skills and devices and the propaganda effects of laparoscopic devices companies contribute in underutilization of VH [19]. With the adoption of formal guidelines, standardised surgical technique and standardized training programs, the proportion of hysterec- tomies performed vaginally will be increased [13,26,30]. In this way, skills and proficiency amongst the registrars is maintained and the benefits of VH will be directly reflected, promoting the patient well-being.

Conclusion

The results of this study demonstrated that VH for the non- prolapsed uterus should be the treatment of choice for benign gynaecologic disease when both vaginal and abdominal modalities are available. LAVH is less cost effective than VH mainly due to a prolonged operating time and the use of disposables.

Declaration of Competing Interest

The authors declare that they have no known competing finan- cial interests or personal relationships that could have appeared to influence the work reported in this paper.

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